UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2024

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _ to

Commission File Number: 001-40431

DAY ONE BIOPHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**83-2415215**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2000 Sierra Point Parkway , Suite 501 Brisbane , CA	**94005**
(Address of principal executive offices)	**(Zip Code)**

(650) 484-0899
(Registrant's telephone number, including area code)

N/A
(Former name, former address and former fiscal year, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	**DAWN**	**Nasdaq Global Select Market**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer		Accelerated filer	
	☒		☐

Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of July 31, 2024, the registrant had

87,760,456
shares of common stock, $0.0001 par value per share, outstanding.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and section 27A of the Securities Act of 1933, as amended, or the Securities Act. All statements contained in this Quarterly Report other than statements of historical fact, including statements regarding our future results of operations and financial position, business strategy, market size, potential growth opportunities, nonclinical and clinical development activities, efficacy and safety profile of OJEMDA™ (tovorafenib) and our product candidates, potential therapeutic benefits and economic value of OJEMDA and product candidates, our ability to market and sell OJEMDA while maintaining full compliance with applicable federal and state laws, rules and regulations, use of net proceeds from our public offerings, our ability to maintain and recognize the benefits of certain designations received by products and product candidates, the timing and results of nonclinical studies and clinical trials, commercial collaboration with third parties, and our ability to recognize milestone and royalty payments from commercialization agreements, the potential impact of global business or macroeconomic conditions, including as a result of inflation, changing interest rates, cybersecurity incidents, actual or perceived instability in the global banking system, uncertainty with respect to the federal debt ceiling and budget and potential government shutdowns related thereto and global regional conflicts on our operations, and the receipt and timing of potential regulatory designations, approvals and commercialization of product candidates, are forward-looking statements. The words “believe,” “may,” “will,” “potentially,” “estimate,” “continue,” “anticipate,” “predict,” “target,” “intend,” “could,” “would,” “should,” “project,” “plan,” “expect,” and other similar expressions that convey uncertainty of future events or outcomes are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in Part II, Item 1A, “Risk Factors” and elsewhere in this Quarterly Report. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Quarterly Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this report to conform these statements to actual results or to changes in our expectations, except as required by law. You should read this Quarterly Report with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

As used in this Quarterly Report on Form 10-Q, the terms “Day One,” “the Company,” “we,” “us,” and “our” refer to Day One Biopharmaceuticals, Inc., a Delaware corporation. “Day One” and all product and product candidate names are our common law trademarks. This Quarterly Report contains additional trade names, trademarks and service marks of other companies, which are the property of their respective owners. We do not intend our use or display of other companies’ trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

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PART I-FINANCIAL INFORMATION

Day One Biopharmaceuticals, Inc.
Condensed Balance Sheets
(in thousands, except share amounts)
(unaudited)

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 239,616	$ 230,784
Short-term investments	122,250	135,563
Accounts receivable, net	9,136	—
Inventory	151	—
Prepaid expenses and other current assets	12,005	8,927
Total current assets	383,158	375,274
Property and equipment, net	196	208
Operating lease right-of-use asset	164	352
Intangible assets, net	16,802	—
Deposits and other long-term assets	117	214
Total assets	$ 400,437	$ 376,048
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 6,444	$ 2,576
Accrued expenses and other current liabilities	87,072	26,524
Current portion of operating lease liability	190	408
Total current liabilities	93,706	29,508
Total liabilities	93,706	29,508
Commitments and contingencies (Note 6)		
Stockholders' equity:		

Common stock, $ 0.0001 par value; 500,000,000 shares authorized as of June 30, 2024 and December 31, 2023; 87,692,916 and 87,227,132 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	9	9
Additional paid-in-capital	832,148	805,107
Accumulated other comprehensive (loss) income	(22)	9
Accumulated deficit	(525,404)	(458,585)
Total stockholders' equity	306,731	346,540
Total liabilities and stockholders' equity	$ 400,437	$ 376,048

See accompanying notes to the condensed financial statements.

Day One Biopharmaceuticals, Inc.
Condensed Statements of Operations
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue:				
Product revenue, net	$ 8,192	$ —	$ 8,192	$ —
Cost and operating expenses:				
Cost of product revenue	707	—	707	—
Research and development	92,106	32,182	132,316	60,010
Selling, general and administrative	30,186	17,072	56,743	35,099
Total cost and operating expenses	122,999	49,254	189,766	95,109
Loss from operations	(114,807)	(49,254)	(181,574)	(95,109)
Non-operating income (expense):				
Gain from sale of priority review voucher	108,000	—	108,000	—
Investment income, net	3,962	3,406	8,327	6,872
Other expense, net	(10)	(15)	(20)	(19)
Total non-operating income, net	111,952	3,391	116,307	6,853
Loss before income taxes	(2,855)	(45,863)	(65,267)	(88,256)
Income tax expense	(1,552)	—	(1,552)	—
Net loss	(4,407)	(45,863)	(66,819)	(88,256)
Net loss per share, basic and diluted	(0.05)	(0.61)	(0.77)	(1.20)
	$	$	$	$
Weighted-average number of common shares used in computing net loss per share, basic and diluted	87,121,310	74,964,878	86,864,545	73,478,567

See accompanying notes to the condensed financial statements.

Day One Biopharmaceuticals, Inc.
Condensed Statements of Comprehensive Loss
(in thousands)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Net loss	$ (4,407)	$ (45,863)	$ (66,819)	$ (88,256)
Other comprehensive income:				
Unrealized (loss) gain on available-for-sale securities	(17)	(76)	(31)	62
Total comprehensive loss	$ (4,424)	$ (45,939)	$ (66,850)	$ (88,194)

See accompanying notes to the condensed financial statements.

Day One Biopharmaceuticals, Inc.
Condensed Statements of Stockholders' Equity
(in thousands, except share amounts)
(unaudited)

	Common Shares		Additional	Accumulated Other	Accumulated	Total Stockholders'
	Shares	Amount	Paid-In Capital	Comprehensive Income (Loss)	Deficit	Equity
Balance at December 31, 2023	87,227,132	$ 9	$ 805,107	$ 9	$ (458,585)	$ 346,540
Issuance of common stock upon exercise of stock options	4,862	—	48	—	—	48
Issuance of common stock upon release of restricted stock units	157,724	—	—	—	—	—
Unvested common stock forfeiture	(12,555)	—	—	—	—	—
Share-based compensation expenses	—	—	12,644	—	—	12,644
Unrealized loss on available-for-sale securities	—	—	—	(14)	—	(14)
Net loss	—	—	—	—	(62,412)	(62,412)
Balance at March 31, 2024	87,377,163	9	817,799	(5)	(520,997)	296,806
Issuance of common stock upon exercise of stock options	22,151	—	324	—	—	324
Issuance of common stock upon release of restricted stock units	211,635	—	—	—	—	—
Issuance of common stock pursuant to Employee Stock Purchase Plan	94,827	—	973	—	—	973
Unvested common stock forfeiture	(12,860)	—	—	—	—	—
Share-based compensation expenses	—	—	13,052	—	—	13,052
Unrealized loss on available-for-sale securities	—	—	—	(17)	—	(17)
Net loss	—	—	—	—	(4,407)	(4,407)
Balance at June 30, 2024	87,692,916	9	832,148	(22)	(525,404)	306,731

See accompanying notes to the condensed financial statements.

Day One Biopharmaceuticals, Inc.
Condensed Statements of Stockholders' Equity
(in thousands, except share amounts)
(unaudited)

	Common Shares		Additional	Accumulated Other	Accumulated	Total Stockholders'
	Shares	Amount	Paid-In Capital	Comprehensive Income (Loss)	Deficit	Equity
Balance at December 31, 2022	73,458,176	$ 7	$ 601,771	$ (71)	$ (269,668)	$ 332,039
Issuance of common stock upon exercise of stock options	75,184	—	1,184	—	—	1,184
Issuance of common stock upon release of restricted stock units	60,673	—	—	—	—	—
Unvested common stock forfeiture	(21,400)	—	—	—	—	—
Share-based compensation expenses	—	—	9,447	—	—	9,447
Unrealized gain on available-for-sale securities	—	—	—	138	—	138
Net loss	—	—	—	—	(42,393)	(42,393)
Balance at March 31, 2023	73,572,633	7	612,402	67	(312,061)	300,415
Issuance of common stock pursuant to follow-on offering, net of issuance costs of $ 10,827	13,269,231	2	161,407	—	—	161,409
Issuance of common stock upon exercise of stock options	2,704	—	39	—	—	39
Issuance of common stock upon release of restricted stock units	69,020	—	—	—	—	—
Issuance of common stock pursuant to Employee Stock Purchase Plan	57,740	—	653	—	—	653
Share-based compensation expenses	—	—	9,477	—	—	9,477
Unrealized loss on available-for-sale securities	—	—	—	(76)	—	(76)
Net loss	—	—	—	—	(45,863)	(45,863)
Balance at June 30, 2023	86,971,328	$ 9	$ 783,978	$ (9)	$ (357,924)	$ 426,054

See accompanying notes to the condensed financial statements.

Day One Biopharmaceuticals, Inc.
Condensed Statements of Cash Flows
(in thousands)
(unaudited)

	Six Months Ended June 30,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (66,819)	$ (88,256)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	25,674	18,924
Depreciation expense	38	12
Accretion of discounts on short-term investments, net	(2,189)	(5,858)
Amortization of intangible assets	298	—
Amortization of operating right-of-use asset	188	169
Gain from sale of priority review voucher	(108,000)	—
Changes in operating assets and liabilities:		
Accounts receivable, net	(9,136)	—
Inventory	(129)	—
Prepaid expenses and other current assets	(3,078)	(1,297)
Deposits and other long-term assets	97	210
Accounts payable	3,868	4,305
Accrued expenses and other current liabilities	60,548	3,569
Operating lease liability	(218)	(195)
Net cash used in operating activities	(98,858)	(68,417)
Cash flows from investing activities:		
Cash paid for purchase of short-term investments	(168,761)	(264,744)
Proceeds from maturity of short-term investments	184,232	274,000

Cash paid for acquired intangible assets	(17,100)	—
Proceeds from sale of priority review voucher	108,000	—
Cash paid for purchase of property and equipment	(26)	(175)
Net cash provided by investing activities	106,345	9,081
Cash flows from financing activities:		
Proceeds from issuance of common stock, net	—	161,409
Proceeds from issuance of common stock upon stock option exercises	372	1,223
Proceeds from issuance of common stock upon Employee Stock Purchase Plan purchase	973	653
Cash provided by financing activities	1,345	163,285
Net increase in cash and cash equivalents	8,832	103,949
Cash and cash equivalents, beginning of period	230,784	85,262
Cash and cash equivalents, end of period	$ 239,616	$ 189,211
Supplemental disclosures of noncash activities:		
Cash not yet paid for upfront license agreement payment	55,000	—
Unpaid/deferred offering costs	—	307

See accompanying notes to the condensed financial statements.

Day One Biopharmaceuticals, Inc.
Notes to the Condensed Financial Statements

1. Description of Business and Organization

Organization and Business

Day One Biopharmaceuticals, Inc., or the Company, is a commercial-stage biopharmaceutical company dedicated to developing and commercializing targeted therapies for people of all ages with life-threatening diseases. The Company was formed as a limited liability company under the laws of the State of Delaware in November 2018, under the name Hero Therapeutics Holding Company, LLC. Subsequently, the Company changed its name to Day One Therapeutics Holding Company, LLC in December 2018 and to Day One Biopharmaceuticals Holding Company, LLC, or Day One Holding LLC, in March 2020. On May 26, 2021, the Company completed a conversion by filing a certificate of conversion with the Secretary of State of the State of Delaware and changed its name to Day One Biopharmaceuticals, Inc.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States, or U.S. GAAP, for interim financial information and Article 10 of Regulation S-X of the Securities and Exchange Commission, or SEC, and should be read in conjunction with the Company's consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on February 26, 2024. The condensed financial statements presented in this Quarterly Report on Form 10-Q are unaudited; however, in the opinion of management, such financial statements reflect all adjustments, consisting solely of normal recurring adjustments, necessary for a fair presentation of the results for the interim periods presented.

Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in Accounting Standards Codification, or ASC, and Accounting Standards Updates, or ASU, of the Financial Accounting Standards Board, or FASB.

Use of Estimates

The preparation of condensed financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and disclosure of contingent assets and liabilities at the date of the condensed financial statements, and the reported amounts of expenses during the reporting period. Estimates and assumptions made in the accompanying condensed financial statements include, but are not limited to, accruals for research and development expenses, variable consideration and other relevant inputs impacting the gross and net revenue recognition, the valuation of share-based awards, and the valuation of deferred tax assets. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable. Actual results may differ from those estimates or assumptions.

Segments

The Company has determined that its chief executive officer is the chief operating decision maker, or CODM. The Company operates and manages the business as one reporting and one operating segment, which is the business of identifying and advancing targeted therapies for people of all ages with genomically-defined cancers. The Company's CODM reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. All of the Company's assets are located in the United States.

Concentration of credit risk and other risks and uncertainties

Financial instruments that subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents, short-term investments, and accounts receivable. Amounts on deposit may at times exceed federally insured limits. The Company is exposed to credit risk in the event of default by the financial institutions holding its cash, cash equivalents and short-term investments that are recorded on its balance sheet. Per policy, the Company mitigates its risk by investing in high-grade instruments and limiting the concentration in any one issuer, which limits its exposure. The Company has not experienced any losses on its cash, cash equivalents and short-term investments.

For the six months ended June 30, 2024, two individual customers accounted for

98
% of total net product revenue, with these individual customers representing

61
% and

37
% of the Company's total net product revenue. As of June 30, 2024, two customers accounted for

98
% of the accounts receivable balance, with these individual customers representing

59
% and

39
% of

the accounts receivable balance. No other individual customers account for more than

10.0

% of net product sales or accounts receivable. The Company monitors the financial condition of its customers so that it can appropriately respond to changes in their creditworthiness. To date, the Company has not experienced any losses with respect to the collection of its accounts receivable.

The Company is subject to certain risks and uncertainties and believes that changes in any of the following areas could have a material adverse effect on the Company's future financial position or results of its operations: ability to obtain future financing; regulatory requirements for approval and market acceptance of, and reimbursement for, product candidates; performance of third-party clinical research organizations and manufacturers upon which the Company relies; development of sales channels; protection of the Company's intellectual property; litigation or claims against the Company based on intellectual property, patent, product, regulatory or other factors; changes to the market landscape; and the Company's ability to attract and retain employees necessary to support its growth.

The Company is dependent on third-party manufacturers to supply products for research and development activities in its programs. In particular, the Company relies and expects to continue to rely on a small number of manufacturers to supply it with its requirements for the active pharmaceutical ingredients and formulated drugs related to these programs. These programs could be adversely affected by a significant interruption in the supply of active pharmaceutical ingredients and formulated drugs.

Accounts Receivable, Net

Accounts receivable, net consists of trade receivables which are amounts due from the Company's specialty pharmacy and specialty distributor customers related to product sales. The Company records trade receivables net of discounts, chargebacks, and any allowances for potential credit losses. An allowance for credit losses is determined based on the financial condition and creditworthiness of customers and the Company considers economic factors and events or trends expected to affect future collections experience. Any allowance would reduce the net receivables to the amount that is expected to be collected. The payment history of the Company's customers will be considered in future assessments of collectability as these patterns are established over a longer period of time. For the three and six months ended June 30, 2024, the Company did

no

t record any expected credit losses related to outstanding accounts receivable.

Inventory

The Company began capitalizing inventory for OJEMDA upon approval by the U.S. Food and Drug Administration, or FDA, in April 2024. OJEMDA is approved for the treatment of patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma, or pLGG, harboring a BRAF fusion rearrangement, or BRAF V600 mutation. Prior to regulatory approval, all direct and indirect manufacturing costs were charged to research and development expense in the period incurred.

Inventory is comprised of raw materials, work-in-process and finished goods, and includes costs related to third-party contract manufacturing, packaging, freight-in and overhead. Inventory is stated at the lower of cost or net realizable value with cost based on the first-in-first-out method. Raw and intermediate materials that may be used for either research and development or commercial purposes where the intended use is not yet known are classified as inventory until the material is consumed or otherwise allocated for research and development. If the material is used or otherwise allocated for research and development, it is expensed as research and development in the period that determination is made.

The Company performs an assessment of the recoverability of capitalized inventory during each reporting period, and it writes down any excess and obsolete inventories to their estimated realizable value in the period in which the impairment is first identified. Such impairment charges, should they occur, are recorded within cost of product revenue. The determination of whether inventory costs will be realizable requires estimates by management. If actual market conditions are less favorable than projected by management, additional write-downs of inventory may be required, which would be recorded as a cost of product revenue in the statements of operations. There were

no

expenses recorded for excess inventory or other impairments during the three and six months ended June 30, 2024.

Product Revenue, Net

The Company recognizes net product revenue from OJEMDA for the treatment of patients 6 months of age and older with relapsed or refractory pLGG harboring a BRAF fusion rearrangement, or BRAF V600 mutation, which it began selling in May 2024 through contractual arrangements with its specialty pharmacy and specialty distributor customers.

The Company recognizes net product revenue in accordance with ASC Topic 606, Revenue from Contracts with Customers, or ASC 606, which outlines a five-step process for recognizing revenue from contracts with customers: (i) identify the contract with the customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the separate performance obligations in the contract, and (v) recognize revenue associated with the performance obligations as they are satisfied. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. Once a contract is determined to be within the scope of ASC 606, the Company determines the performance obligations that are

distinct. The Company recognizes as revenues the amount of the transaction price that is allocated to each respective performance obligation when the performance obligation is satisfied. The Company has determined that the delivery of OJEMDA to its customers constitutes a single performance obligation. There are no other promises to deliver goods or services beyond what is specified in each accepted customer order. Net product revenue is recognized at the transaction price when the customer obtains control of the Company's product, which occurs at a point in time upon delivery of the product to the customer.

The Company has assessed the existence of a significant financing component in the agreements with its customers. The trade payment terms with the Company's customers do not exceed one year and therefore the Company has elected to apply the practical expedient and no amount of consideration has been allocated as a financing component.

Net product revenues from the sale of OJEMDA are recorded at the transaction price, which include adjustments for discounts and allowances, including estimated cash discounts, government chargebacks, government rebates, specialty distributor fees, copay assistance, and returns. These adjustments represent variable consideration under ASC 606 and are estimated using the expected value method or most likely amount method and are recorded when revenue is recognized on the sale of the product. These adjustments are established by management as its best estimate based on available information and will be adjusted to reflect known changes in the factors that impact such allowances. Adjustments for variable consideration are determined based on the contractual terms with customers, historical trends, communications with customers and the levels of inventory remaining in the distribution channel, as well as expectations about the market for the product and anticipated introduction of competitive products. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the respective underlying contracts.

The amount of variable consideration which is included in the transaction price may be constrained, and is included in the net sales price, only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under the contract will not occur in a future period. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's original estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

Cash Discounts — The Company estimates cash discounts based on contractual terms and expectations regarding future customer payment patterns. The adjustments are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable.

Government Chargebacks — Chargebacks for fees and discounts to qualified government healthcare providers represent the estimated obligations resulting from contractual commitments to sell products to qualified U.S. Department of Veterans Affairs hospitals and 340B entities at prices lower than the list prices charged to customers who directly purchase the product from the Company. The 340B Drug Discount Program is a U.S. federal government program created in 1992 that requires drug manufacturers to provide outpatient drugs to eligible health care organizations and covered entities at significantly reduced prices. Customers charge the Company for the difference between what they pay for the product and the statutory selling price to the qualified government entity. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivables, net. Chargeback amounts are generally determined at the time of resale to the qualified government healthcare provider by customers, and the Company generally issues credits for such amounts within a few weeks of the Customer's notification to the Company of the resale. Reserves for chargebacks consist of chargebacks that customers have claimed, but for which the Company has not yet issued a credit and credits that the Company expects to issue for product that has been recognized as revenue, but which remains in the distribution channel inventories at the end of each reporting period.

Government Rebates — The Company is subject to discount obligations under state Medicaid programs and Medicare. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities. For Medicare, the Company also estimates the number of patients in the prescription drug coverage gap for whom the Company will owe an additional liability under the Medicare Part D program. For Medicaid programs, the Company estimates the portion of sales attributed to Medicaid patients and records a liability for the rebates to be paid to the respective state Medicaid programs. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but which remains in the distribution channel inventories at the end of each reporting period.

Specialty Distributor Fees — The Company pays fees to our specialty distributor customers for distribution services provided in connection with the sales of OJEMDA. These specialty distributor fees are based on a contractually determined fixed percentage of sales. The adjustments are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities.

Copay Assistance — The Company offers a co-pay assistance program, which is intended to provide financial assistance to qualified commercially-insured patients with prescription drug co-payments required by payers. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that the Company expects to receive associated with product that has been recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period. The adjustments are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included as accrued expenses and other current liabilities.

Product Returns — Consistent with industry practice, the Company's contracts with customers for OJEMDA generally provide for returns only if the product is damaged or defective upon delivery, if there is a shipment error, and for certain customers, if the product is within an eligible expiry window. The Company currently estimates product return reserves using available industry data and its own sales information, including its visibility into the inventory remaining in the distribution channel. The Company believes the returns of OJEMDA will be minimal because our customers often carry limited inventory given the price of our products, and the limited number of patients. These reserves are established in the same period that the related revenue is recognized.

Cost of Product Revenue

Our cost of product revenue includes the cost of inventory sold, amortization expense of intangible assets and third-party royalties payable on our net product revenue. Cost of goods sold may also include costs related to excess or obsolete inventory adjustment charges, abnormal costs, unabsorbed manufacturing and overhead costs, and manufacturing variances.

Intangible Assets, Net

Upon FDA approval and commercial launch of OJEMDA in April 2024, the Company capitalized the $

9.0

million milestone payment to Viracta Therapeutics, Inc. (f/k/a Sunesis Pharmaceuticals, Inc.), or Viracta, for a specified regulatory milestone as a finite-lived intangible asset. Upon the sale of the Priority Review Voucher, or PRV, in May 2024 to fully satisfy PRV-related obligations of the Company's license agreement with Viracta, dated December 16, 2019, as amended, the Company capitalized the $

8.1

million payment to Viracta as a finite-lived intangible asset. The intangible assets will be amortized on a straight-line basis over each of the estimated useful life of the underlying intellectual property of 7.3 years. Amortization expense will be recorded as cost of product revenue.

Recently Issued Accounting Pronouncements

In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280) – Improvements to Reportable Segment Disclosures, which requires incremental disclosure of segment information on an interim and annual basis. This ASU is effective for public entities for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Retrospective application to all prior periods presented in the financial statements is required for public entities. The Company is currently evaluating the effect of this update on its financial statement disclosures.

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740) – Improvements to Income Tax Disclosures, which enhances the transparency and decision usefulness of income tax disclosures by requiring disclosure of disaggregated income taxes paid, prescribes standard categories for the components of the effective tax rate reconciliation, and modifies other income tax-related disclosures. The ASU is effective for fiscal years beginning after December 15, 2024 and allows for adoption on a prospective basis, with a retrospective option. The Company is currently evaluating the effect of this update on its financial statement disclosures.

3. Recurring Fair Value Measurements

The following table sets forth the Company's financial instruments as of June 30, 2024 and December 31, 2023, which are measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	June 30, 2024			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$ 8,658	$ —	$ —	$ 8,658
U.S. treasury securities	—	181,583	—	181,583
U.S. government agency securities	—	96,037	—	96,037
Total assets measured at fair value	$ 8,658	$ 277,620	$ —	$ 286,278

	December 31, 2023			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$ 47,003	$ —	$ —	$ 47,003
U.S. treasury securities	—	246,208	—	246,208
U.S. government agency securities	—	63,202	—	63,202
Total assets measured at fair value	$ 47,003	$ 309,410	$ —	$ 356,413

The Company's money market funds are classified as Level 1 because they are measured using observable inputs from active markets for identical assets.

The Company's U.S. treasury securities and U.S. government agency securities are classified as Level 2 because they are measured with inputs that are either directly or indirectly observable for the asset which include quoted prices for similar assets in active markets and quoted prices for identical or similar assets in markets that are not active.

There were no assets or liabilities classified as Level 3 as of June 30, 2024 and December 31, 2023.

There were

no

transfers between Level 1, Level 2 or Level 3 categories during the periods presented.

The following tables summarize the estimated fair value of the Company's cash equivalents, available-for-sale securities classified as short-term investments, and associated unrealized gains and losses (in thousands):

	June 30, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Cash equivalents:				
Money market funds	$ 8,658	$ —	$ —	$ 8,658
U.S. government agency securities	59,607	—	—	59,607
U.S. treasury securities	95,763	—	—	95,763
Total cash equivalents	164,028	—	—	164,028
Short-term investments				
U.S. government agency securities	36,445	—	(15)	36,430
U.S. treasury securities	85,827	—	(7)	85,820
Total short-term investments	122,272	—	(22)	$ 122,250

	December 31, 2023			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Cash equivalents:				

Money market funds				
	47,003	—	—	47,003
	$	$	$	$
U.S. government agency securities				
	63,202	—	—	63,202
U.S. treasury securities				
	110,645	—	—	110,645
Total cash equivalents				
	220,850	—	—	220,850
Short-term investments				
U.S. treasury securities				
	135,554	9	—	135,563
Total short-term investments				
	135,554	9	—	135,563
	$	$	$	$

The following table summarizes the maturities of our cash equivalents and available-for-sale securities (in thousands):

	June 30, 2024	
	Amortized Cost	Fair Value
Mature in one year or less		
	286,300	286,278
	$	$
Total		
	286,300	286,278
	$	$

	December 31, 2023	
	Amortized Cost	Fair Value
Mature in one year or less		
	356,404	356,413
	$	$
Total		
	356,404	356,413
	$	$

The Company regularly reviews the changes to the rating of its securities and monitors the surrounding economic conditions to assess the risk of expected credit losses. As of June 30, 2024 and December 31, 2023, there were

no

securities that

were in an unrealized loss position for more than 12 months. As of June 30, 2024, the unrealized losses, if any, on the Company's short-term investments were primarily caused by interest rate increases. The Company does not expect the issuers to settle any security at a price less than the amortized cost basis of the investment with the contractual cash flows of these investments guaranteed by the issuer. No allowance for credit losses has been recorded since it is not more-likely-than-not that the Company will be required to sell the investments before recovery of their amortized cost basis.

4. Balance Sheet Items

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	June 30, 2024	December 31, 2023
Prepaid research and development expenses	$ 7,611	$ 5,657
Prepaid insurance	1,928	918
Other prepaid expenses and other assets	2,466	2,352
Total prepaid expenses and other current assets	$ 12,005	$ 8,927

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	June 30, 2024	December 31, 2023
Accrued license agreement upfront payment	$ 55,000	$ —
Accrued research and development expenses	18,332	12,643
Accrued payroll related expenses	6,601	9,165
Accrued professional service expenses	4,007	3,675
Other	3,132	1,041
Total accrued expenses and other current liabilities	$ 87,072	$ 26,524

5. Significant Agreements

Takeda asset purchase agreement

On December 16, 2019, a subsidiary of the Company entered into an asset purchase agreement, or the Takeda Asset Agreement, with Millennium Pharmaceuticals, Inc., a related party and an affiliate of Takeda Pharmaceutical Company Limited, or Takeda. Effective December 31, 2021, the subsidiary was merged with and into the Company, with the Company being the surviving corporation and assuming the subsidiary's obligations under the Takeda Assets Purchase Agreement. Pursuant to the Takeda Asset Agreement, the Company purchased certain technology rights and know-how related to TAK-580 (which is now OJEMDA™ (tovorafenib)) that provides a new approach for treating patients with primary brain tumors or brain metastases of solid tumors. The Company also received clinical inventory supplies to use in the Company's research and development activities of such RAF-inhibitor and an assigned investigator clinical trial agreement. Takeda also assigned to the Company its exclusive license agreement, or the Viracta License Agreement, with Viracta. Takeda also granted the Company a worldwide, sublicensable exclusive license under specified patents and know-how and non-exclusive license under other patents and know-how generated by Takeda under the Takeda Asset Agreement. The Company also granted Takeda a grant back license, as defined in the Takeda Asset Agreement, which is

terminable either automatically or by the Company in the event Takeda does not achieve specified development milestones within the applicable timeframes set forth under the Takeda Asset Agreement. This grant back license to Takeda was terminated at the time of conversion in connection with the Millennium Stock Exchange Agreement.

The term of the Takeda Asset Agreement will expire on a country-by-country basis upon expiration of all assigned patent rights and all licensed patent rights in such country. Takeda may terminate the Takeda Asset Agreement prior to the Company's first commercial sale of a product if the Company ceases conducting any development activities for a continuous and specified period of time and such cessation is not agreed upon by the parties and is not done in response to guidance from a regulatory authority. Additionally, Takeda can terminate the Takeda Asset Agreement in the event of the Company's bankruptcy. In the event of termination of the Takeda Asset Agreement by Takeda as a result of the Company's cessation of development or bankruptcy, all assigned patents, know-how and contracts (other than the Viracta License Agreement) will be assigned back to Takeda and Takeda will obtain a reversion license under patents and know-how generated to exploit all such terminated products.

In consideration for the sale and assignment of assets and the grant of the license under the Takeda Asset Agreement, the Company made an upfront payment of $

1.0
million in cash and issued

9,857,143
shares of Series A redeemable convertible

preferred stock in the Company's subsidiary in December 2019. The fair value of issued shares was estimated as $

9.9

million, based on the price paid by other investors for issued shares in the Series A financing of the Company's subsidiary. Based on the terms of the Millennium Stock Exchange Agreement, Takeda exchanged the

9,857,143

shares of Series A redeemable convertible preferred stock of the Company's subsidiary for

6,470,382

shares of the Company's common stock upon the effectiveness of the conversion, on May 26, 2021.

License agreement with Viracta

On December 16, 2019, a subsidiary of the Company amended and restated the Viracta License Agreement that was assigned pursuant to the Takeda Asset Agreement. Effective December 31, 2021, the subsidiary was merged with and into the Company, with the Company being the surviving corporation and assuming the subsidiary's obligations under Viracta License Agreement. Under the Viracta License Agreement, the Company received a worldwide exclusive license under specified patent rights and know-how to develop, use, manufacture, and commercialize products containing compounds binding the RAF protein family.

The term of the Viracta License Agreement will expire on a licensed product-by-licensed product and country-by-country basis upon the expiration of the Company's obligation to pay royalties to Viracta with respect to such product in such country. The Company has the right to terminate the Viracta License Agreement with respect to any or all of the licensed products at will upon a specified notice period.

The Company paid $

2.0

million upfront in cash to Viracta, which was recorded as research and development expenses as the technology does not have an alternative future use.

On March 4, 2024, the Company entered into an amendment to the Viracta License Agreement. As part of the amendment, the Company made a one-time payment in March 2024 to Viracta of $

5.0

million, which was recorded as research and development expenses during the six months ended June 30, 2024, in exchange for reduced future payment obligations ranging from the mid-teens to the high single-digit percentage related to the future sale or use of the rare pediatric disease PRV received.

On April 23, 2024, the FDA approved OJEMDA (a tablet formulation and powder solution formulation of tovorafenib) for the treatment of patients 6 months of age and older with relapsed or refractory pLGG harboring a BRAF fusion or rearrangement, or BRAF V600 mutation. The indication was approved under accelerated approval based on response rate and duration of response. With the approval, the Company received a rare pediatric disease PRV from the FDA. The Company made a $

9.0

million milestone payment to Viracta in May 2024 for the achievement of this milestone. The $

9.0

million milestone was accounted for as a finite-lived intangible asset and will be amortized over the life of the underlying asset. Related amortization expense will be recorded as cost of product revenue in the Company's statements of operations.

On May 29, 2024, the Company sold its rare pediatric disease PRV for $

108.0

million to an undisclosed buyer. As part of the transaction, $

8.1

million of the total consideration received from the sale of the rare pediatric disease PRV was paid to Viracta to fully satisfy PRV-related obligations under the Viracta License Agreement. The gross proceeds of $

108.0

million were recorded as a gain from sale of priority review voucher in the accompanying condensed statements of operations during the three and six months ended June 30, 2024. As of June 30, 2024, the $

8.1

million paid to satisfy PRV-related obligations was capitalized as a finite-lived intangible asset, which will be amortized on a straight-line basis over its estimated useful life. Related amortization expense will be recorded as cost of product revenue in the Company's statements of operations.

As of June 30, 2024, the Company could be required to make additional milestone payments of up to $

40.0

million upon achievement of specified development and regulatory milestones for each licensed product in two indications, with milestones payable for the second indication upon achievement of a specified milestone event being lower than milestones payable for the first indication. Commencing with the first commercial sale of OJEMDA in a country, the Company is obligated to pay tiered royalties ranging in the mid-single-digit percentages on net sales of licensed products. The obligation to pay royalties will end on a country-by-country and licensed product-by-licensed product basis commencing on the first commercial sale in a country and continuing until the later of: (i) the expiration of the last valid claim of the Viracta licensed patents, jointly owned collaboration patents or specified patents owned by the Company covering the use or sale of such product in such country, (ii) the expiration of the last statutory exclusivity pertaining to such product in such country or (iii) the tenth anniversary of the first commercial sale of such product in such country.

License agreement with Merck KGaA, Darmstadt, Germany

On February 10, 2021, a subsidiary of the Company entered into a license agreement, or the MRKDG License Agreement, with Merck KGaA, Darmstadt, Germany, a pharmaceutical corporation located in Darmstadt, Germany. Effective December 31, 2021, the subsidiary was merged with and into the Company, with the Company being the surviving corporation and assuming the subsidiary's obligations under the

Under the MRKDG License Agreement, Merck KGaA, Darmstadt, Germany granted to the Company an exclusive worldwide license, with the right to grant sublicenses through multiple tiers, under specified patent rights and know-how for the Company to research, develop, manufacture and commercialize products containing and comprising the pimasertib and MSC2015103B compounds. The Company also received clinical inventory supplies to use in its research and development activities. The Company's exclusive license grant is subject to a non-exclusive license granted by Merck KGaA, Darmstadt, Germany's affiliate to a cancer research organization and Merck KGaA, Darmstadt, Germany retains the right to conduct, directly or indirectly, certain ongoing clinical studies relating to pimasertib. Under the MRKDG License Agreement, the Company has obligations to use commercially reasonable efforts to develop and commercialize at least two licensed products in at least two specified major market countries by the year 2029.

The term of the MRKDG License Agreement will expire on a licensed product-by-licensed product and country-by-country basis upon the expiration of the Company's obligation to pay royalties to the licensor with respect to such licensed product in such country and will expire in its entirety upon the expiration of all of the Company's payment obligations with respect to all licensed products and all countries under the MRKDG License Agreement.

In consideration for the rights granted under the MRKDG License Agreement and clinical supplies, the Company made an upfront payment of $

8.0

million, which was recorded as research and development expenses, as the technology does not have an alternative future use and supplies are used for research activities. As of June 30, 2024, the Company could be required to make additional payments of up to $

364.5

million based upon the achievement of specified development, regulatory, and commercial milestones, as well a high, single-digit royalty percentage on future net sales of licensed products, if any. Milestones and royalties are contingent upon future events and will be recorded when the milestones are achieved and when payments are due.

Research collaboration and license agreement with Sprint Bioscience AB

On August 15, 2023, the Company entered into a research collaboration and license agreement, or the Sprint License Agreement, with Sprint Bioscience AB, or Sprint, a Swedish corporation located in Huddinge, Sweden. Under the Sprint License Agreement, Sprint granted to the Company an exclusive, worldwide license, with the right to grant sublicenses through multiple tiers, to research, develop, and commercialize pharmaceutical products and to engage in research aimed at discovery, optimization and development of Vaccinia Related Kinase 1, or VRK1.

The term of the Sprint License Agreement will expire on a licensed product and country basis upon the expiration of the royalty term with respect to such licensed product and such country, unless terminated earlier. The Company has the right to terminate the Sprint License Agreement in its entirety, or on a licensed product-by-licensed product basis, at will upon a specified notice period.

The Company paid $

3.0

million upfront in cash to Sprint, which was recorded as research and development expenses as the technology does not have an alternative future use. As of June 30, 2024, the Company could be required to make milestone payments of up to $

309.0

million based upon achievement of specified development, regulatory, and commercial milestones for each licensed product, as well as tiered royalties ranging in the single-digit percentages on future net sales of licensed products, if any. Milestones and royalties are contingent upon future events and will be recorded when the milestones are achieved and when payments are due.

License agreement with MabCare Therapeutics

On June 17, 2024, the Company entered into a license agreement, or the MabCare License Agreement, with MabCare Therapeutics, or MabCare, a pharmaceutical corporation located in Shanghai, China. Under the MabCare License Agreement, MabCare granted to the Company an exclusive worldwide license, excluding Greater China, with the right to grant sublicenses through multiple tiers, under specified patent rights and know-how for the Company to develop, manufacture and commercialize DAY301 (formerly MTX-13), a novel Antibody Drug Conjugate, or ADC, targeting protein-tyrosine kinase 7, or PTK7. The Company will also receive clinical inventory supplies to use in its research and development activities. Under the MabCare License Agreement, the Company has obligations to use commercially reasonable efforts to develop, obtain regulatory approval for, and commercialize at least one licensed product in one indication in each of the United States, Japan, and three European countries.

The term of the MabCare License Agreement will expire in its entirety upon the expiration of the last to expire royalty term with respect to all licensed products in the Company's territory, unless terminated earlier. Following the expiration of the royalty term for a licensed product in a country, the license grant to the Company shall become non-exclusive, fully paid-up, royalty-free, perpetual, and irrevocable for such licensed product in such country. Upon the expiration of the term, the license granted to the Company shall become non-exclusive, transferable, sublicensable, fully paid, royalty free, perpetual, and irrevocable in its entirety.

In consideration for the rights granted under the MabCare License Agreement, the Company accrued a $

55.0

million upfront payment as a liability as of June 30, 2024, which was paid in July 2024. The upfront payment was recorded as research and development expenses, as the technology and supplies licensed do not have an alternative future use. As of June 30, 2024,

the Company could be required to make additional payments of $

1,152.0

million based upon the achievement of specified development, regulatory, and commercial success-based milestones plus low-to-mid single-digit royalties on net sales outside of Greater China. Milestones and royalties are contingent upon future events and will be recorded when the milestones are achieved and when payments are due.

6. Commitments and Contingencies

Leases

In April 2022, the Company entered into a lease agreement for approximately

12,000

square feet of general use office space in Brisbane, California. Such agreement was determined to be a lease since the right to control the use of the identified asset was conveyed to the Company for a period of time in exchange for consideration. The term of the lease is 31 months and commenced in May 2022. There is no option to extend the lease term nor is there an option to terminate the lease term prior to its expiration. The Company is obligated to pay monthly rent expense and its pro rata share of the landlord's operating expenses which include utilities, common area maintenance expenses, and property taxes. Such expenses are a non-lease component and a variable consideration and included in the Company's operating expenses as incurred. The Company concluded that this lease is also an operating lease. The total payments for base rent over the term of the lease is approximately $

1.1

million. Upon execution of the agreement, the Company paid a security deposit of approximately $

40,000

classified as deposits and other long-term assets on the condensed balance sheet.

In June 2024, the Company entered into a lease agreement for approximately

19,000

square feet of general use office space in Brisbane, California. Such agreement was determined to be a lease since the right to control the use of the identified asset was conveyed to the Company for a period of time in exchange for consideration. The term of the lease is approximately 7.1 years. There is no option to extend the lease term nor is there an option to terminate the lease term prior to its expiration. The Company is obligated to pay monthly rent expense and its pro rata share of the landlord's operating expenses which include utilities, common area maintenance expenses, and property taxes. Such expenses are a non-lease component and a variable consideration and included in the Company's operating expenses as incurred. The Company concluded that this lease is also an operating lease. As of June 30, 2024, this lease has not yet commenced. The total payments for base rent over the term of the lease is approximately $

4.4

million.

The Company determined the lease incremental borrowing rate, or IBR, based on the information available at the applicable lease commencement date as the Company’s leases do not provide an implicit rate. The IBR is determined by using the rate of interest that the Company would pay to borrow on a collateralized basis an amount equal to the lease payments for a similar term and in a similar economic environment where the asset is located. As of June 30, 2024, for the lease entered into in April 2022, the weighted-average remaining lease term and weighted-average discount rate were 0.4 years and

9.0

%, respectively.

The Company’s lease does not require any contingent rental payments, impose financial restrictions, or contain any residual value guarantees.

Lease expense of right-of-use assets is recognized on a straight-line basis over the applicable lease term. Lease expense was $

0.1

million for each of the three months ended June 30, 2024 and 2023 and was $

0.2

million for each of the six months ended June 30, 2024 and 2023. Cash paid for amounts included in the measurement of operating lease liabilities was $

0.2

million for each of the six months ended June 30, 2024 and 2023. Variable payments expensed during the three and six months ended June 30, 2024 and 2023 were immaterial.

As of June 30, 2024, the future lease obligations for the lease entered into in April 2022 were as follows (in thousands):

	June 30, 2024
Remaining in 2024	$ 193
Total future minimum lease payments	193

Less: imputed interest	(3)
Present value of operating lease liabilities	190
Less: current portion of operating lease liabilities	(190)
Operating lease liabilities	$ -

Research and Development Agreements

The Company enters into contracts in the normal course of business with clinical research organizations, contract manufacturing organizations, and other third-party vendors for clinical trial, manufacturing, testing, and other research and development activities. These contracts generally provide for termination on notice, with the exception of one vendor where certain costs are non-cancellable after the approval of the project. As of June 30, 2024 and December 31, 2023, there were

no

amounts accrued related to termination and cancellation charges as these are not probable.

License Agreements

The Company entered into license agreements, as disclosed in Note 5, with various parties under which it is obligated to make contingent and non-contingent payments.

Purchase Commitments

To support product needs for OJEMDA, the Company has entered into a manufacturing and supply agreement with Quotient Sciences - Philadelphia, LLC in July 2023 that requires the Company to meet minimum purchase obligations on an annual basis. The amount of future minimum purchase obligations under the manufacturing and supply agreement over the next five years is approximately $

16.7

million, in aggregate, as of June 30, 2024. For the six months ended June 30, 2024, the Company made purchases of $

0.5

million under the purchase obligation.

Legal Proceedings

The Company, from time to time, may be party to litigation, claims and assessments arising in the ordinary course of business. The Company accrues liabilities for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. The Company is not subject to any material legal proceedings, and to the best of its knowledge, no material legal proceedings are currently pending or threatened.

Indemnification Agreements

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for indemnification for certain liabilities. The exposure under these agreements is unknown because it involves claims that may be made against it in the future but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations. The Company also has indemnification obligations to its directors and executive officers for specified events or occurrences, subject to some limits, while they are serving at its request in such capacities. There have been no claims to date, and the Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company had

no

t recorded any liabilities for these agreements as of June 30, 2024 and December 31, 2023.

7. Common Stock

Pursuant to its certificate of incorporation, the Company is authorized to issue

500

.0 million shares of common stock at a par value of $

0.0001

per share. As of June 30, 2024,

87,692,916

shares of common stock were issued and outstanding.

The Company has reserved shares of common stock for future issuances as follows:

	June 30, 2024
Common stock options issued and outstanding	12,203,622
Common stock available for future grants	3,716,936
Common stock available for ESPP	2,498,360
Restricted stock units issued and outstanding	1,916,588
Total	20,335,506

June 2023 Follow-On Offering

In June 2023, the Company completed a follow-on offering and issued and sold

13,269,231

shares of common stock (including the exercise by the underwriters of their option to purchase an additional

1,730,769

shares of common stock) at a price to the public of $

13.00
per share for net proceeds of approximately $

161.4
million, after deducting underwriting discounts, commissions, and offering costs.

At-The-Market Offering

The Company has entered into an equity distribution agreement, or the Equity Distribution Agreement, with Piper Sandler & Co. and JonesTrading Institutional Services LLC, as sales agents, relating to the issuance and sale of shares of the Company's common stock for an aggregate offering price of up to $

250.0
million under an at-the-market offering program, or the ATM. The Company has no obligation to sell any shares and could at any time suspend solicitations and offers under the ATM. No shares of the Company's common stock have been sold under the ATM as of June 30, 2024.

8. Share-based Compensation

Share-based compensation expense recorded in the accompanying condensed statements of operations is as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Research and development expense	$ 4,709	$ 3,410	$ 9,362	$ 6,790
Selling, general and administrative expense	8,321	6,067	16,312	12,134
Total share-based compensation expense	$ 13,030	$ 9,477	$ 25,674	$ 18,924

2022 Equity Inducement Plan

In October 2022, the board of directors and stockholders approved the 2022 Equity Inducement Plan, or the 2022 Plan. The 2022 Plan provides for the grant of non-statutory stock options and restricted stock units. The number of shares of common stock reserved for issuance under the 2022 Plan is

1,000,000
shares.

2021 Equity Incentive Plan

In May 2021, in connection with the IPO, the board of directors and stockholders approved, the 2021 Equity Incentive Plan, or the 2021 Plan, which became effective on the day before the date of the effectiveness of the IPO. The 2021 Plan provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, awards of restricted stock, restricted stock units and other share-based awards. The number of shares of common stock reserved for issuance under the 2021 Plan is equal to the sum of: (x)

6,369,000
shares of common stock; plus (y)

4,719,605
shares of common stock issued in respect of the conversion of incentive shares that were subject to vesting immediately prior to the effectiveness of the registration statement for the IPO that expire, terminate or are otherwise surrendered, canceled, forfeited or repurchased by us at their original issuance price pursuant to a contractual repurchase right. The number of shares available for grant and issuance under the 2021 Plan will be automatically increased on the first day of each fiscal year, beginning with the fiscal year commencing on January 1, 2021 and continuing for each fiscal year until, and including, the fiscal year commencing on January 1, 2031, by the lesser of (a)

5
% of the number of shares of all classes of the Company's common stock, plus the total number of shares of Company common stock issuable upon conversion of any preferred stock or exercise of any warrants to acquire shares of Company common stock for a nominal exercise price issued and outstanding on each December 31 immediately prior to the date of increase or (b) such number of shares determined by the board of directors.

Stock Options

The following table provides a summary of stock option activity during the six months ended June 30, 2024.

	Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2023	10,211,758	$ 17.10		
Granted	2,597,862	$ 14.36		
Exercised	(27,013)	$ 13.76		$ 68
Forfeiture	(578,985)	$ 16.89		
Outstanding at June 30, 2024	12,203,622	$ 16.54	7.9	$ 2,237

Vested and expected to vest at June 30, 2024	12,203,622	$ 16.54	7.9	$ 2,237
Exercisable at June 30, 2024	6,400,855	$ 16.68	7.3	$ 1,011

Aggregate intrinsic value represents the difference between the estimated fair value of the underlying common stock and the exercise price of outstanding, in-the-money options. The total intrinsic value of options exercised during the six months ended June 30, 2024 and 2023 was less than $

0.1
million and $

0.6
million, respectively.

The total fair value of options that vested during the six months ended June 30, 2024 and 2023 was $

17.9
million and $

12.8
million, respectively. The weighted-average grant date fair value of options granted during the six months ended June 30, 2024 and 2023 was $

9.26
per share and $

13.81
per share, respectively.

Unamortized share-based compensation for stock options as of June 30, 2024 was $

59.6
million, which is expected to be recognized over a weighted-average period of 2.4 years.

The Company used the Black-Scholes option pricing model to estimate the fair value of stock option awards granted with the following assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Expected term (in years)	5.3 - 6.1	5.3 - 6.2	5.3 - 6.7	5.3 - 6.3
Expected volatility	68.57% - 69.18%	69.21% - 81.65%	68.27% - 70.57%	69.21% - 81.98%
Risk-free interest rate	4.24% - 4.47%	3.47% - 3.98%	3.90% - 4.47%	3.47% - 4.08%
Expected dividend yield	—	—	—	—

Restricted Stock Units

The following table provides a summary of restricted stock units activity during the six months ended June 30, 2024:

	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Unvested restricted stock units at December 31, 2023	1,031,545	$ 18.27
Granted	1,430,880	$ 14.45
Vested	(369,359)	$ 16.63
Forfeiture	(176,478)	$ 16.41
Unvested restricted stock units at June 30, 2024	1,916,588	$ 15.90

Unamortized share-based compensation for restricted stock units as of June 30, 2024 was $ 28.7 million, which is expected to be recognized over a weighted-average period of 3.0 years.

Restricted Stock Awards

The following table provides a summary of the unvested common stock awards activity during the six months ended June 30, 2024.

	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Unvested common stock as of December 31, 2023	747,679	$ 16.00
Vested	(376,591)	$ 16.00

Forfeiture	(25,415)	$ 16.00
Unvested common stock as of June 30, 2024	345,673	$ 16.00

Unamortized share-based compensation for restricted stock awards as of June 30, 2024 was $ 1.9 million, which is expected to be recognized over a weighted-average period of 0.7 years.

2021 Employee Stock Purchase Plan

In May 2021, the board of directors adopted and the stockholders approved the 2021 Employee Stock Purchase Plan, or the ESPP, which became effective on May 26, 2021. A total of 603,000 shares of common stock were initially reserved for issuance under the ESPP. The number of shares of the common stock reserved for issuance under the ESPP will automatically increase on the first day of each fiscal year, beginning with the fiscal year commencing on January 1, 2021 and continuing for each fiscal year until, and including, the fiscal year commencing on January 1, 2031, by the lesser of: (a) 1% of the total number of outstanding shares of common stock of the Company (on an as converted basis outstanding on the immediately preceding December 31 (rounded down to the nearest whole share)) and (b) an amount determined by the board of directors.

331,014 shares have been issued under the ESPP as of June 30, 2024. The Company recognized compensation expense related to the ESPP of $ 0.2 million and $ 0.3 million for the three months ended June 30, 2024 and 2023, respectively, and $ 0.4 million and $ 0.5 million for the six months ended June 30, 2024 and 2023, respectively.

The fair value of our common stock to be issued under the ESPP is estimated at the date of grant using a Black-Scholes option-pricing model with the following assumptions:

	Six Months Ended June 30,	
	2024	**2023**
Expected term (in years)	0.5	0.5
Expected volatility	63.45 %	63.57 %
Risk-free interest rate	5.40 %	5.24 %
Expected dividend yield	—	—

9. Income Taxes

For the three and six months ended June 30, 2024, the Company recognized income tax expense of $ 1.6 million resulting in an effective tax rate of (54.4)% and (2.4)%, respectively. The primary reconciling items between the federal statutory rate of 21.0 % for the three and six months ended June 30, 2024 and the Company's overall effective tax rate of (54.4)% and (2.4)%, respectively, was the effect of equity compensation, generation of tax credits, deferred state income taxes and the valuation allowance recorded against the full amount of its net deferred tax assets. The Company did no t record an income tax provision for the three and six months ended June 30, 2023 as it generated tax losses during each of the periods.

A valuation allowance is established when it is more likely than not that some portion or all of a deferred tax asset will not be realized. The realization of deferred tax assets depends on the generation of future taxable income during the period in which related temporary differences become deductible. The Company continues to establish a valuation allowance against the full amount of its net deferred tax assets since it is more likely than not that benefits will not be realized, including those benefits created in the current year. This assessment is based on the Company's historical cumulative losses, which provide strong objective evidence that cannot be overcome with projections of income, as well as the fact the Company expects continuing losses in the future.

10. Net Loss Per Share

Basic and diluted net loss per share attributable to common stockholders is calculated as follows (in thousands except share and per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Net loss	$ (4,407)	$ (45,863)	$ (66,819)	$ (88,256)
Net loss per share, basic and diluted	$ (0.05)	$ (0.61)	$ (0.77)	$ (1.20)
Weighted-average number of common shares used in computing net loss per share, basic and diluted	87,121,310	74,964,878	86,864,545	73,478,567

The following outstanding potentially dilutive securities have been excluded from the calculation of diluted net loss per share, as their effect is anti-dilutive:

	As of June 30,	
	2024	2023
Stock options	12,203,622	9,933,697
Unvested common shares	345,673	1,202,257

Restricted stock units	1,916,588	999,509
Shares committed under ESPP	90,306	69,578
Total	14,556,189	12,205,041

11. Defined Contribution Plan

The Company maintains an employee savings plan pursuant to Section 401(k) of the Internal Revenue Code. All employees are eligible to participate provided that they meet the requirements of the plan. For each of the three months ended June 30, 2024 and 2023, the Company made matching contributions of $

0.4
million and $

0.3
million, respectively. For the six months ended June 30, 2024 and 2023, the Company made matching contributions of $

1.0
million and $

0.8
million, respectively.

12. Subsequent Events

Ipsen License Agreement

On July 23, 2024, the Company and Ipsen Pharma SAS, or Ipsen, entered into an Exclusive License Agreement, or the Ipsen License Agreement, pursuant to which the Company will license to Ipsen, on an exclusive basis, the right to commercialize tovorafenib outside the United States.

In consideration for the rights and licenses granted by the Company to Ipsen in the Ipsen License Agreement, Ipsen will pay the Company (i) an upfront license fee in the amount of approximately $

71.0
million within thirty days after the effective date of the Ipsen License Agreement and (ii) Ipsen Biopharmaceuticals, Inc. (USA), or the Investor, a fully-owned Affiliate, as defined in the Ipsen License Agreement, of Ipsen, agreed to purchase shares of the Company's common stock, or the Company Share Issuance, for $

40.0
million, at a price per share representing a

17.0
% premium to the volume weighted average price of the Company's common stock as traded on The Nasdaq Stock Market LLC for the ten consecutive trading days prior to and including the date of the Company's public release of U.S. GAAP revenue for the quarter ended June 30, 2024, or the Revenue Release, and the ten consecutive trading days following the Revenue Release, in accordance with the terms set forth in a certain investment agreement by and between the Company and the Investor dated July 23, 2024.

The Company is also eligible to receive up to approximately $

350.0
million in launch and sales milestones as well as tiered, double-digit royalty payments starting at mid-teens percentage of annual net sales of OJEMDA, subject to certain adjustments specified in the Ipsen License Agreement. The royalty payment obligations under the Ipsen License Agreement expire on a country-by-country basis no earlier than ten years following the first commercial sale of OJEMDA in the applicable country.

The Company will account for the Ipsen License Agreement under the provisions of ASC 606. The Company will estimate the standalone selling price of each performance obligation to allocate the transaction price and recognize revenue for each performance obligation when the associated goods or services are transferred. The Company expects a portion of the transaction price received under the Ipsen License Agreement shall be deferred into future periods as each performance obligation is not expected to be fully satisfied at contract inception.

2024 Private Placement

On July 30, 2024, the Company entered into a securities purchase agreement, or the Securities Purchase Agreement, with certain institutional and accredited investors, or Investors, pursuant to which the Company agreed to sell and issue to the Investors in a private placement, or the Private Placement, an aggregate of (i)

10,551,718
shares, or the Shares, of the Company's common stock, par value $

0.0001
per share, or the Common Stock, at a purchase price of $

14.50
per share and (ii)

1,517,241
pre-funded warrants, or the Pre-Funded Warrants, to purchase up to an aggregate of

1,517,241
shares of Common Stock, or the Warrant Shares, and together with the Shares and the Pre-Funded Warrants, or the Securities, at a purchase price of $

14.4999
per Pre-Funded Warrant. Each Pre-Funded Warrant has an exercise price of $

0.0001
per Warrant Share. The Pre-Funded Warrants are exercisable at any time after their original issuance and will not expire.

The Private Placement closed on August 1, 2024. The Company received gross proceeds from the Private Placement of approximately $

175.0

million, before deducting placement agent fees and other expenses.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes, our interim condensed financial statements and related notes, and other financial information appearing in our Annual Report on Form 10-K for the year ended December 31, 2023, or our Annual Report, and this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" in this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

Day One is a biopharmaceutical company founded to address a critical unmet need: the dire lack of therapeutic development in pediatric cancer. Our name was inspired by the “The Day One Talk” that physicians have with patients and their families about an initial cancer diagnosis and treatment plan. We aim to re-envision cancer drug development and redefine what’s possible for all people living with cancer—regardless of age—starting from Day One.

Our lead product, tovorafenib, is an oral, brain-penetrant, highly selective type II rapidly accelerated fibrosarcoma, or RAF, kinase inhibitor. Tovorafenib was granted breakthrough therapy designation by the U.S. Food and Drug Administration, or the FDA, in August 2020 for the treatment of relapsed or refractory low-grade glioma, or pLGG, based on initial results from a Phase 1 trial which showed evidence of rapid anti-tumor activity and durable responses in patients with pLGG. Pediatric low-grade glioma is the most common brain tumor diagnosed in children. While new targeted therapeutic options have recently become available for patients with pLGG, there is no consensual standard of care and a vast majority of patients with pLGG do not yet have access to approved therapies. Tovorafenib received orphan drug designation for the treatment of malignant glioma from the FDA in September 2020 and from the EU Commission for the treatment of glioma in May 2021. Additionally, the FDA granted rare pediatric disease designation to tovorafenib for treatment of low-grade gliomas, or LGGs, harboring an activating RAF alteration in July 2021.

On April 23, 2024, we announced that the FDA approved OJEMDA™ (tovorafenib) for the treatment of patients 6 months of age and older with relapsed or refractory pLGG harboring a BRAF fusion or rearrangement, or BRAF V600 mutation. The indication was approved under accelerated approval based on response rate and duration of response. With the approval, we received a rare pediatric disease priority review voucher, or PRV, from the FDA. We have commenced the commercial launch of OJEMDA in the United States. OJEMDA is the only systemic therapy for pLGG that offers once-weekly dosing, with or without food, as a tablet or oral suspension.

The accelerated approval of OJEMDA is based on data from the Company’s pivotal open-label Phase 2 FIREFLY-1 trial, which enrolled a total of 137 relapsed or refractory BRAF-altered pLGG patients across two study arms. Arm 1, which accrued 77 patients, was used for the efficacy analyses. Arm 2 provided additional safety data from an incremental 60 patients and was initiated to enable access to OJEMDA once Arm 1 had fully accrued. Details of this trial were presented in November 2023 at the Society for Neuro-Oncology meeting through two oral plenary presentations and in parallel through a publication in Nature Medicine.

The approval of OJEMDA was based, in part, on the major efficacy outcome measure of overall response rate, or ORR, defined as the proportion of patients with complete response, partial response, or PR, or minor response, or MR, by independent review based on Response Assessment in Pediatric Neuro-Oncology Low-Grade Glioma, or RAPNO LGG.

In Arm 1, data from the 76 RAPNO LGG evaluable patients include:

- A best ORR of 51% (95% CI: 40 - 63), which included 28 PRs and 11 MRs.
- The ORR for OJEMDA was 52% among the 64 patients with BRAF fusions or rearrangements and 50% for the 12 patients with a BRAF V600 mutation.
- The ORR was 49% among the 45 patients who had received a prior MAPK-targeted therapy, and 55% among the 31 patients who had not received a prior MAPK-targeted therapy.
- As of the June 5, 2023 data cutoff, the median duration of response by RAPNO LGG was 13.8 months (95% CI: 11.3, not estimable). In addition, 66% of patients remained on study and continue on treatment as of this date.
- The median time to response, following initiation of treatment, with OJEMDA was 5.3 months (range 1.6 months, 11.2 months).
- Based on RANO LGG criteria, the ORR was 53% [95% CI: (41, 64)].

The safety of OJEMDA was evaluated in 137 patients with relapsed or refractory pLGG, with the majority of adverse events being Grade 1 or Grade 2. The most common side effects were rash, hair color changes, tiredness, viral infection, vomiting, headache, fever, dry skin, constipation, nausea, acne and upper respiratory tract infection.

We initiated a pivotal Phase 3 trial, or FIREFLY-2, evaluating tovorafenib as a front-line therapy in patients ages 6 months to 25 years with pLGG in June 2022. The first patient was dosed in FIREFLY-2 in March 2023. To date, patients continue to enroll in the United States, Canada, Europe, Australia and Asia, with approximately 100 sites activated. In June 2024, we announced the following changes to our FIREFLY-2 trial: the primary endpoint of objective response rate will be assessed according to the RAPNO-LGG criteria, key secondary endpoints of progression free survival and duration of response will be assessed according to RAPNO-LGG

criteria, new patients will be initiated on a starting dose of 380 mg/m^2/dose once weekly, and the addition of a once-monthly carboplatin regime as a fourth standard of care option for arm 2.

On July 23, 2024, we entered into an Exclusive License Agreement, or the Ipsen License Agreement, with Ipsen Pharma SAS, or Ipsen, pursuant to which we will license to Ipsen, on an exclusive basis, the right to commercialize tovorafenib outside the United States.

In consideration for the rights and licenses granted by us to Ipsen in the Ipsen License Agreement, Ipsen will pay us (i) an upfront license fee in the amount of approximately $71.0 million within thirty days after the effective date of the Ipsen License Agreement and (ii) Ipsen Biopharmaceuticals, Inc. (USA), or the Investor, a fully-owned Affiliate of Ipsen, agreed to purchase shares of our common stock, or the Company Share Issuance, for $40.0 million, at a price per share representing a 17.0% premium to the volume weighted average price of our common stock as traded on The Nasdaq Stock Market LLC for the ten consecutive trading days prior to and including the date of our public release of U.S. GAAP revenue for the quarter ended June 30, 2024, or the Revenue Release, and the ten consecutive trading days following the Revenue Release, in accordance with the terms set forth in a certain investment agreement by and between us and the Investor dated July 23, 2024, or the Investment Agreement.

We are also eligible to receive up to approximately $350.0 million in launch and sales milestones as well as tiered, double-digit royalty payments starting at mid-teens percentage of annual net sales of OJEMDA, subject to certain adjustments specified in the Ipsen License Agreement. The royalty payment obligations under the Ipsen License Agreement expire on a country-by-country basis no earlier than ten years following the first commercial sale of OJEMDA in the applicable country.

Our product candidate, pimasertib, is an oral, highly selective small molecule inhibitor of mitogen-activated protein kinase kinases 1 and 2, or MEK, a well-characterized key signaling node in the MAPK pathway. Pimasertib has been studied in more than 10 Phase 1/2 clinical trials in over 850 patients with various tumor types, both as a monotherapy and in combination with standard of care therapies. Published preclinical studies indicated that pimasertib has higher central nervous system penetration than other MEK inhibitors.

We initiated an open-label, multicenter, Phase 1b/2a umbrella master trial, or FIRELIGHT-1, of tovorafenib as a monotherapy or in combination, which consists of two substudies. Substudy 1 is a Phase 2a trial of tovorafenib as a monotherapy in patients 12 years and older with relapsed, progressive, or refractory solid tumors harboring a RAF alteration (RAF fusion or amplification). Despite observing responses with a generally well tolerated therapy, a limited duration of response in this rare patient population was observed. We decided in November 2023 to discontinue this monotherapy substudy and re-direct resources to other programs. Results from the substudy will be shared for presentation or publication after the final dataset becomes available. Substudy 2 is a Phase 1b/2 combination trial of tovorafenib and pimasertib in patients 12 years and older with various MAPK-altered solid tumors. Despite observing some clinical responses, the benefit/risk profile, as well as the market opportunity, did not justify the significant investment required to continue the trial. Moreover, it is clear from competing efforts to combine other Type II RAF inhibitors with MEK inhibitors that the hoped-for therapeutic benefit of the combination was more limited than preclinical studies predicted. We decided in July 2024 to close the program. Results from the substudy will be shared for presentation at a future medical meeting or publication.

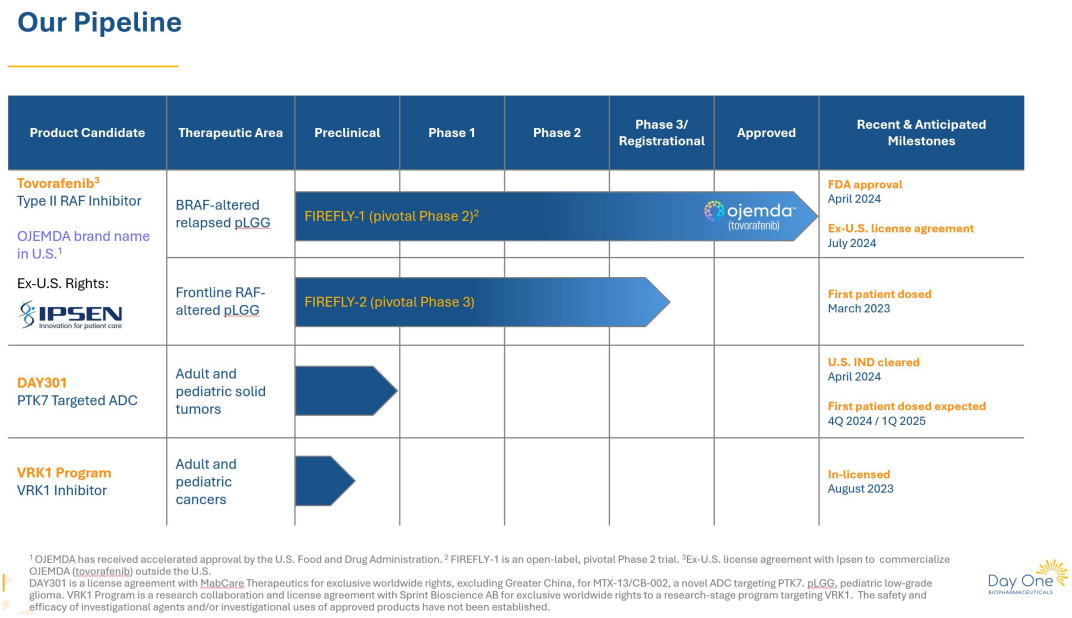
In August 2023, we entered into a research collaboration and license agreement, or the Sprint License Agreement, with Sprint Bioscience AB, or Sprint, a Swedish corporation located in Huddinge, Sweden. Under the Sprint License Agreement, Sprint granted to us an exclusive, worldwide license, with the right to grant sublicenses through multiple tiers, to research, develop, and commercialize pharmaceutical products and to engage in research aimed at discovery, optimization and development of Vaccinia Related Kinase 1, or VRK1. VRK1 is a novel target involved in the regulation of cell division and DNA damage repair. Over-expression of VRK1 is linked to poor prognosis in a variety of adult and pediatric cancers, and VRK1 has been identified as a synthetic lethal target in tumors where expression of its paralog, VRK2, is lost. Silencing of VRK2 expression via promoter methylation has been noted in most high-grade gliomas and high-risk neuroblastomas, providing a concrete approach for selecting patients with tumors sensitive to VRK1 inhibition. Preclinical research activities to advance the VRK1 program are ongoing.

In June 2024, we entered into a license agreement, or the MabCare License Agreement, with MabCare Therapeutics, or MabCare, a pharmaceutical corporation located in Shanghai, China. Under the MabCare License Agreement, MabCare granted to us an exclusive worldwide license, excluding Greater China, with the right to grant sublicenses through multiple tiers, under specified patent rights and know-how for the Company to develop, manufacture and commercialize DAY301 (formerly MTX-13 or CB-002). DAY301 is a novel Antibody Drug Conjugate, or ADC, targeting protein-tyrosine kinase 7, or PTK7. In April 2024, the FDA cleared the investigational new drug application for DAY301. In pre-clinical studies, DAY301 showed antitumor activity in a wide range of solid tumors. DAY301 targets PTK7, a highly-conserved, catalytically inactive transmembrane protein that is overexpressed in multiple adult cancers, including esophageal, ovarian, lung, and endometrial cancer, as well as pediatric cancers such as neuroblastoma, rhabdomyosarcoma and osteosarcoma.

We believe our business development capabilities combined with our extensive experience in oncology drug development and deep ties within the research and patient advocacy communities, particularly within the pediatric setting, positions us to be a leader in identifying, acquiring and developing therapies for patients of all ages. We hold exclusive rights to develop tovorafenib and pimasertib for all therapeutic areas worldwide subject to certain milestone and royalty payments. Further, we hold exclusive rights to commercialize tovorafenib in the United States subject to royalty payments. Pursuant to the Ipsen License Agreement, we licensed to

Ipsen, on an exclusive basis, the right to commercialize tovorafenib outside of the United States, in exchange for certain milestone and royalty payments.

The following table summarizes our product and product candidate pipeline.



Significant Agreements

Takeda asset purchase agreement

On December 16, 2019, our subsidiary entered into an asset purchase agreement, or the Takeda Asset Agreement, with Millennium Pharmaceuticals, Inc., a related party and an affiliate of Takeda Pharmaceutical Company Limited, or Takeda. Effective December 31, 2021, the subsidiary was merged with and into our company, with our company being the surviving corporation and assuming the subsidiary's obligations under the Takeda Assets Purchase Agreement. Pursuant to the Takeda Asset Agreement, we purchased certain technology rights and know-how related to TAK-580 (which is now OJEMDA) that provides a new approach for treating patients with primary brain tumors or brain metastases of solid tumors. We also received clinical inventory supplies to use in our research and development activities of such RAF-inhibitor and an assigned investigator clinical trial agreement. Takeda also assigned us its exclusive license agreement, or the Viracta License Agreement, with Viracta. Takeda also granted us a worldwide, sublicensable exclusive license under specified patents and know-how and non-exclusive license under other patents and know-how generated by Takeda under the Takeda Asset Agreement. We also granted Takeda a grant back license, as defined in the Takeda Asset Agreement, which is terminable either automatically or by us in the event Takeda does not achieve specified development milestones within the applicable timeframes set forth under the Takeda Asset Agreement. This grant back license to Takeda was terminated at the time of conversion in connection with the Millennium Stock Exchange Agreement.

The term of the Takeda Asset Agreement will expire on a country-by-country basis upon expiration of all assigned patent rights and all licensed patent rights in such country. Takeda may terminate the Takeda Asset Agreement prior to our first commercial sale of a product if we cease conducting any development activities for a continuous and specified period of time and such cessation is not agreed upon by the parties and is not done in response to guidance from a regulatory authority. Additionally, Takeda can terminate the Takeda Asset Agreement in the event of our bankruptcy. In the event of termination of the Takeda Asset Agreement by Takeda as a result of our cessation of development or bankruptcy, all assigned patents, know-how and contracts (other than the Viracta License Agreement) will be assigned back to Takeda and Takeda will obtain a reversion license under patents and know-how generated to exploit all such terminated products.

In consideration for the sale and assignment of assets and the grant of the license under the Takeda Asset Agreement, we made an upfront payment of $1.0 million in cash and issued 9,857,143 shares of our Series A redeemable convertible preferred stock in our subsidiary in December 2019. The fair value of issued shares was estimated as $9.9 million, based on the price paid by other investors for issued shares in the Series A financing of our subsidiary. Based on the terms of the Millennium Stock Exchange Agreement,

Takeda exchanged the 9,857,143 shares of Series A redeemable convertible preferred stock of our subsidiary for 6,470,382 shares of our common stock upon the effectiveness of the conversion, on May 26, 2021.

License agreement with Viracta

On December 16, 2019, we amended and restated the Viracta License Agreement that was assigned pursuant to the Takeda Asset Agreement. Effective December 31, 2021, our subsidiary was merged with and into our company, with our company being the surviving corporation and assuming our subsidiary's obligations under Viracta License Agreement. Under the Viracta License Agreement, we received a worldwide exclusive license under specified patent rights and know-how to develop, use, manufacture, and commercialize products containing compounds binding the RAF protein family.

The term of the Viracta License Agreement will expire on a licensed product-by-licensed product and country-by-country basis upon the expiration of the Company's obligation to pay royalties to Viracta with respect to such product in such country. We have the right to terminate the Viracta License Agreement with respect to any or all of the licensed products at will upon a specified notice period.

We paid $2.0 million upfront in cash to Viracta, which was recorded as research and development expenses as the technology does not have an alternative future use.

On March 4, 2024, we entered into an amendment to the Viracta License Agreement. As part of the amendment, we made a one-time payment in March 2024 to Viracta of $5.0 million, which was recorded as research and development expenses during the six months ended June 30, 2024, in exchange for reduced future payment obligations ranging from the mid-teens to the high single-digit percentage related to the future sale or use of the rare pediatric disease PRV received.

On April 23, 2024, the FDA approved OJEMDA (a tablet formulation and powder solution formulation of tovorafenib) for the treatment of patients 6 months of age and older with relapsed or refractory pLGG harboring a BRAF fusion or rearrangement, or BRAF V600 mutation. The indication was approved under accelerated approval based on response rate and duration of response. With the approval, we received a rare pediatric disease PRV from the FDA. We made a $9.0 million milestone payment to Viracta in May 2024 for the achievement of this milestone. The $9.0 million milestone was accounted for as a finite-lived intangible asset and will be amortized over the life of the underlying asset. Related amortization expense will be recorded as cost of product revenue in our statements of operations.

On May 29, 2024, we sold our rare pediatric disease PRV for $108.0 million to an undisclosed buyer. As part of the transaction, $8.1 million of the total consideration received from the sale of the rare pediatric disease PRV was paid to Viracta to fully satisfy PRV-related obligations under the Viracta License Agreement. The gross proceeds of $108.0 million were recorded as a gain from sale of priority review voucher in the accompanying condensed statements of operations during the three and six months ended June 30, 2024. As of June 30, 2024, the $8.1 million paid to satisfy PRV-related obligations was capitalized as a finite-lived intangible asset, which will be amortized on a straight-line basis over its estimated useful life. Related amortization expense will be recorded as cost of product revenue in the Company's statements of operations.

As of June 30, 2024, we could be required to make additional milestone payments of up to $40.0 million upon achievement of specified development and regulatory milestones for each licensed product in two indications, with milestones payable for the second indication upon achievement of a specified milestone event being lower than milestones payable for the first indication. Commencing with the first commercial sale of OJEMDA in a country, we are obligated to pay tiered royalties ranging in the mid-single-digit percentages on net sales of licensed products. The obligation to pay royalties will end on a country-by-country and licensed product-by-licensed product basis commencing on the first commercial sale in a country and continuing until the later of: (i) the expiration of the last valid claim of the Viracta licensed patents, jointly owned collaboration patents or specified patents owned by us covering the use or sale of such product in such country, (ii) the expiration of the last statutory exclusivity pertaining to such product in such country or (iii) the tenth anniversary of the first commercial sale of such product in such country.

License agreement with Merck KGaA, Darmstadt, Germany

On February 10, 2021, our subsidiary entered into a license agreement, or the MRKDG License Agreement, with Merck KGaA, Darmstadt, Germany, a pharmaceutical corporation located in Darmstadt, Germany. Effective December 31, 2021, the subsidiary was merged with and into our company, with our company being the surviving corporation and assuming the subsidiary's obligations under the MRKDG License Agreement. Under the MRKDG License Agreement, Merck KGaA, Darmstadt, Germany granted to us an exclusive worldwide license, with the right to grant sublicenses through multiple tiers, under specified patent rights and know-how for us to research, develop, manufacture and commercialize products containing and comprising the pimasertib and MSC2015103B compounds. We also received clinical inventory supplies to use in its research and development activities. Our exclusive license grant is subject to a non-exclusive license granted by Merck KGaA, Darmstadt, Germany's affiliate to a cancer research organization and Merck KGaA, Darmstadt, Germany retains the right to conduct, directly or indirectly, certain ongoing clinical studies relating to pimasertib. Under the MRKDG License Agreement, we have obligations to use commercially reasonable efforts to develop and commercialize at least two licensed products in at least two specified major market countries by the year 2029.

The term of the MRKDG License Agreement will expire on a licensed product-by-licensed product and country-by-country basis upon the expiration of our obligation to pay royalties to the licensor with respect to such licensed product in such country and will expire in its entirety upon the expiration of all of our payment obligations with respect to all licensed products and all countries under the MRKDG License Agreement.

In consideration for the rights granted under the MRKDG License Agreement and clinical supplies, we made an upfront payment of $8.0 million, which was recorded as research and development expenses, as the technology does not have an alternative future use and supplies are used for research activities. As of June 30, 2024, we could be required to make additional payments of up to $364.5 million based upon the achievement of specified development, regulatory, and commercial milestones, as well a high, single-digit royalty percentage on future net sales of licensed products, if any. Milestones and royalties are contingent upon future events and will be recorded when the milestones are achieved and when payments are due.

Research collaboration and license agreement with Sprint Bioscience AB

On August 15, 2023, we entered into the Sprint License Agreement. Under the Sprint License Agreement, Sprint granted to us an exclusive, worldwide license, with the right to grant sublicenses through multiple tiers, to research, develop, and commercialize pharmaceutical products and to engage in research aimed at discovery, optimization and development of VRK1.

The term of the Sprint License Agreement will expire on a licensed product and country basis upon the expiration of the royalty term with respect to such licensed product and such country, unless terminated earlier. We have the right to terminate the Sprint License Agreement in its entirety, or on a licensed product-by-licensed product basis, at will upon a specified notice period.

We paid $3.0 million upfront in cash to Sprint, which was recorded as research and development expenses as the technology does not have an alternative future use. As of June 30, 2024, we could be required to make milestone payments of up to $309.0 million based upon achievement of specified development, regulatory, and commercial milestones for each licensed product, as well as tiered royalties ranging in the single-digit percentages on future net sales of licensed products, if any. Milestones and royalties are contingent upon future events and will be recorded when the milestones are achieved and when payments are due.

License agreement with MabCare Therapeutics

On June 17, 2024, we entered into the MabCare License Agreement. Under the MabCare License Agreement, MabCare granted to us an exclusive worldwide license, excluding Greater China, with the right to grant sublicenses through multiple tiers, under specified patent rights and know-how for us to develop, manufacture and commercialize DAY301, a novel ADC targeting PTK7. We will also receive clinical inventory supplies to use in our research and development activities. Under the MabCare License Agreement, we have obligations to use commercially reasonable efforts to develop, obtain regulatory approval for, and commercialize at least one licensed product in one indication in each of the United States, Japan, and three European countries.

The term of the MabCare License Agreement will expire in its entirety upon the expiration of the last to expire royalty term with respect to all licensed products in our territory, unless terminated earlier. Following the expiration of the royalty term for a licensed product in a country, the license grant to us shall become non-exclusive, fully paid-up, royalty-free, perpetual, and irrevocable for such licensed product in such country. Upon the expiration of the term, the license granted to us shall become non-exclusive, transferable, sublicensable, fully paid, royalty free, perpetual, and irrevocable in its entirety.

In consideration for the rights granted under the MabCare License Agreement, we made an upfront payment of $55.0 million, which was recorded as research and development expenses, as the technology does not have an alternative future use. As of June 30, 2024, the Company could be required to make additional payments of $1,152.0 million based upon the achievement of specified development, regulatory, and commercial success-based milestones plus low-to-mid single-digit royalties on net sales outside of Greater China. Milestones and royalties are contingent upon future events and will be recorded when the milestones are achieved and when payments are due.

Components of Results of Operations

Revenue

Product revenue, net

In April 2024, the FDA approved OJEMDA for the treatment of patients 6 months of age and older with relapsed or refractory pLGG harboring a BRAF fusion or rearrangement, or BRAF V600 mutation. In May 2024, we began to generate revenue from sales

of OJEMDA in the United States. We record product revenue net of estimated discounts, chargebacks, rebates, specialty distributor fees, copay assistance, and product returns.

Operating expenses

Cost of product revenue

Cost of product revenue includes the cost of inventory sold, amortization expense of intangible assets and third-party royalties payable on our net product revenue. Cost of goods sold may also include costs related to excess or obsolete inventory adjustment charges, abnormal costs, unabsorbed manufacturing and overhead costs, and manufacturing variances.

Research and development expenses

Research and development expenses consist primarily of external and internal expenses incurred for our research activities, including our discovery and in-licensing undertakings, and the development of our product candidates.

External expenses include:

- costs incurred under agreements with third-party contract research organizations, or CROs, contract manufacturing organizations, or CMOs, and other third parties that conduct clinical trials on our behalf;
- costs associated with acquiring technology and intellectual property licenses that have no alternative future uses; and
- other business operational costs, such as rent, facilities and maintenance, travel and information technology, incurred related to research and development activities, but are not allocable to a specific product or product candidate.

Internal expenses include:

- employee-related costs, including salaries, bonuses, benefits and share-based compensation expense, for our research and development personnel.

We expense research and development expenses as incurred. We track external costs by program, which currently consist of expenses for our OJEMDA, pimasertib, and VRK1 programs. We do not track indirect costs on a program specific basis because these costs are deployed across multiple programs and, as such, are not separately classified.

Research and development activities are central to our business model. We expect that our research and development expenses will increase for the foreseeable future as we continue to implement our business strategy; advance our product candidates through clinical trials and conduct larger clinical trials; expand our research and development efforts; and identify, acquire and develop additional product candidates, particularly as more of our product candidates move into clinical development and later stages of clinical development.

The successful development of our drug candidates is uncertain and subject to a number of risks. We cannot guarantee that results of clinical trials will be favorable or sufficient to support marketing authorizations for any of our product development programs. We could decide to abandon development or be required to spend considerable resources not otherwise contemplated. For additional discussion regarding the risks and uncertainties regarding our research and development programs, please refer to Part II, Item 1A “Risk Factors” in this Quarterly Report on Form 10-Q.

Selling, general and administrative expenses

Selling, general and administrative expenses consist primarily of employee-related costs, professional services and other operational costs. Employee-related costs include salaries, bonuses, benefits and share-based compensation expense for our selling, general and administrative personnel. Professional service expenses include legal fees; professional fees for accounting, marketing, human resources, business development, and other consulting services. Other operational costs include expenses for rent and facilities maintenance, travel, insurance and information technology.

We expect that our selling, general and administrative expenses will increase for the foreseeable future as we anticipate an increase in our personnel headcount to support the expansion of our corporate and commercial activities and continued expenses associated with being a public company, including costs related to compliance with the requirements of the Nasdaq Global Select Market, or Nasdaq, and the Securities and Exchange Commission, or the SEC; and investor and public relations costs.

Gain from sale of priority review voucher

Gain from the sale of priority review voucher represents the sale of our rare pediatric disease PRV, which was awarded to us in connection with the FDA’s approval of OJEMDA.

Results of operations

Comparison of three months ended June 30, 2024 and 2023

The following table summarizes our results of operations for the three months ended June 30, 2024 and 2023 (unaudited):

	Three Months Ended June 30,			
	2024	2023	$ Change	% Change
Revenue:				
Product revenue, net	$ 8,192	$ —	$ 8,192	*
Cost and operating expenses:				
Cost of product revenue	707	—	707	*
Research and development	92,106	32,182	59,924	186.2%
Selling, general and administrative	30,186	17,072	13,114	76.8%
Total cost and operating expenses	122,999	49,254	73,745	149.7%
Loss from operations	(114,807)	(49,254)	(65,553)	133.1%
Non-operating income (expense):				
Gain from sale of priority review voucher	108,000	—	108,000	*
Investment income, net	3,962	3,406	556	16.3%
Other expense, net	(10)	(15)	5	(33.3)%
Total non-operating income, net	111,952	3,391	108,561	*
Loss before income taxes	(2,855)	(45,863)	43,008	(93.8)%
Income tax expense	(1,552)	—	(1,552)	*
Net loss	$ (4,407)	$ (45,863)	$ 41,456	(90.4)%

* Amount and/or percentage not meaningful

Product revenue, net

For the three months ended June 30, 2024, we recorded net product revenue of $8.2 million from sales of OJEMDA in the United States.

Cost of product revenue

For the three months ended June 30, 2024, we recorded cost of product revenue of $0.6 million related to sales of OJEMDA in the United States. Prior to the FDA approval of OJEMDA, product costs were expensed as research and development expense.

Research and development expenses

Research and development expenses increased $59.9 million, from $32.2 million for the three months ended June 30, 2023 to $92.1 million for the three months ended June 30, 2024. Third-party expenses increased by $2.9 million due primarily to an increase in clinical trial and manufacturing activities, personnel related expenses increased by $1.6 million driven by headcount growth, and other research and development costs increased by $0.4 million. Additionally, during the three months ended June 30, 2024, expense of $55.0 million was recorded for the upfront payment due per the terms of the MabCare License Agreement.

The following table summarizes our external and internal research and development expenses for the three months ended June 30, 2024 and 2023:

	Three Months Ended June 30,	
	2024	2023
	(in thousands)	
External costs:		
Third-party CRO, CMO and other third-party clinical trial costs (1)	$ 22,547	$ 19,646
MabCare license agreement upfront payment	55,000	—
Other research and development costs	2,346	1,901
Internal costs:		
Employee related expenses	12,213	10,635
Total research and development expenses	$ 92,106	$ 32,182

(1) Third-party CRO, CMO and other clinical trial costs for the tovorafenib, pimasertib, and VRK1 programs were $19.3 million, $1.5 million, and $1.7 million, respectively, for three months ended June 30, 2024 compared to $19.0 million, $0.6 million, and $0, respectively, for the three months ended June 30, 2023.

Selling, general and administrative expenses

Selling, general and administrative expenses increased $13.1 million, from $17.1 million for the three months ended June 30, 2023 to $30.2 million for the three months ended June 30, 2024. The increase in selling, general and administrative expenses was

primarily due to an increase of $6.8 million in personnel related expenses driven by headcount growth, an increase of $5.1 million in professional services driven by commercial launch activities, and an increase of $1.2 million in other selling, general and administrative costs.

Gain from sale of priority review voucher

Gain from sale of priority review voucher for the three months ended June 30, 2024 was $108.0 million related to the sale of our rare pediatric disease PRV, which was awarded to us in connection with the FDA's approval of OJEMDA.

Income tax expense

Income tax expense for the three months ended June 30, 2024, was $1.6 million resulting in an effective tax rate of (54.4%) driven by the effect of equity compensation, generation of tax credits, deferred state income taxes and the valuation allowance recorded against the full amount of our net deferred tax assets. The Company did not record an income tax provision for the three months ended June 30, 2023 as it generated tax losses during the period.

Comparison of six months ended June 30, 2024 and 2023

The following table summarizes our results of operations for the six months ended June 30, 2024 and 2023 (unaudited):

	Six Months Ended June 30,			
	2024	2023	$ Change	% Change
Revenue:				
Product revenue, net	$ 8,192	$ —	8,192	*
Cost and operating expenses:				
Cost of product revenue	707	—	707	*
Research and development	132,316	60,010	72,306	120.5%
Selling, general and administrative	56,743	35,099	21,644	61.7%
Total cost and operating expenses	189,766	95,109	94,657	99.5%
Loss from operations	(181,574)	(95,109)	(86,465)	90.9%
Non-operating income (expense):				
Gain from sale of priority review voucher	108,000	—	108,000	*
Investment income, net	8,327	6,872	1,455	21.2%
Other expense, net	(20)	(19)	(1)	5.3%
Total non-operating income, net	116,307	6,853	109,454	*
Loss before income taxes	(65,267)	(88,256)	22,989	(26.0)%
Income tax expense	(1,552)	—	(1,552)	*
Net Loss	$ (66,819)	$ (88,256)	$ 21,437	(24.3)%

* Amount and/or percentage not meaningful

Product revenue, net

For the six months ended June 30, 2024, we recorded net product revenue of $8.2 million from sales of OJEMDA in the United States.

Cost of product revenue

For the six months ended June 30, 2024, we recorded cost of product revenue of $0.6 million related to sales of OJEMDA in the United States. Prior to the FDA approval of OJEMDA, the majority of costs were expensed as research and development expense.

Research and development expenses

Research and development expenses increased $72.3 million, from $60.0 million for the six months ended June 30, 2023 to $132.3 million for the six months ended June 30, 2024. Third-party expenses increased by $6.6 million, due primarily to an increase in clinical trial, manufacturing, and other product development expenses, personnel related expenses increased by $4.5 million resulting from additional headcount and stock-based compensation, and other research and development expenses increased by $1.2 million. Milestone expense increased by $60.0 million due to a $55.0 million upfront fee related to the MabCare License Agreement and a $5.0 million amendment payment related to the Viracta License Agreement.

The following table summarizes our external and internal research and development expenses for the six months ended June 30, 2024 and 2023:

	Six Months Ended June 30,	
	2024	2023
	(in thousands)	
External costs:		
Third-party CRO, CMO and other third-party clinical trial costs (1)	$ 42,093	$ 35,497
MabCare license agreement upfront payment	55,000	—
Viracta license agreement amendment payment	5,000	—
Other research and development costs	4,513	3,283
Internal costs:		
Employee related expenses	25,710	21,230
Total research and development expenses	$ 132,316	$ 60,010

(1) Third-party CRO, CMO and other clinical trial costs for the tovorafenib, pimasertib, and VRK1 programs were $36.1 million, $2.5 million, and $3.5 million, respectively, for six months ended June 30, 2024 compared to $33.7 million, $1.8 million, and $0, respectively, for the six months ended June 30, 2023.

Selling, general and administrative expenses

Selling, general and administrative expenses increased $21.6 million, from $35.1 million for the six months ended June 30, 2023 to $56.7 million for the six months ended June 30, 2024. The increase in selling, general and administrative expenses was primarily due to an increase of $11.9 million in personnel related expenses driven by headcount growth, an increase of $6.8 million in professional services driven by commercial launch activities, and an increase of $2.9 million in other selling, general and administrative costs.

Gain from sale of priority review voucher

Gain from sale of priority review voucher for the six months ended June 30, 2024 was $108.0 million related to the sale of our rare pediatric disease PRV, which was awarded to us in connection with the FDA's approval of OJEMDA.

Income tax expense

Income tax expense for the six months ended June 30, 2024, was $1.6 million resulting in an effective tax rate of (2.4%) driven by the effect of equity compensation, generation of tax credits, deferred state income taxes and the valuation allowance recorded against the full amount of our net deferred tax assets. The Company did not record an income tax provision for the six months ended June 30, 2023 as it generated tax losses during the period.

Liquidity and Capital Resources

Sources of liquidity

In June 2023, we completed a follow-on offering and issued and sold 13,269,231 shares of common stock (including the exercise by the underwriters of their option to purchase an additional 1,730,769 shares of common stock) at a price to the public of $13.00 per share for net proceeds of approximately $161.4 million, after deducting underwriting discounts, commissions, and offering costs.

We have entered into an equity distribution agreement, or the Equity Distribution Agreement, with Piper Sandler & Co. and JonesTrading Institutional Services LLC, as sales agents, relating to the issuance and sale of shares of our common stock for an aggregate offering price of up to $250.0 million under an at-the-market offering program, or the ATM. No shares of our common stock have been sold under the ATM as of June 30, 2024.

As of June 30, 2024, we had an accumulated deficit of $525.4 million and $361.9 million in cash and cash equivalents and short-term investments. We believe our cash and cash equivalents and short-term investments will be sufficient to satisfy our cash requirements at least twelve months after the date that this Quarterly Report is filed.

Our primary use of cash is to fund operating expenses, which consist of research and development expenditures and selling, general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses. Our material cash requirements include the following contractual and other obligations.

Leases

We have an operating lease obligation for office space. As of June 30, 2024, we had fixed lease payment obligations of approximately $0.2 million payable within 12 months.

Contract Research Organizations and Contract Manufacturing Organizations

We have entered into contracts in the normal course of business with CROs, CMOs, and other third-party vendors for clinical trial, manufacturing, testing, and other research and development activities. These contracts generally provide for termination on notice, with the exception of one vendor where certain costs are non-cancellable after the approval of the project. As of June 30, 2024, there were no amounts accrued related to termination and cancellation charges as these are not probable.

License Agreements

Under our license agreements, we have payment obligations that are contingent upon future events such as our achievement of specified development, regulatory and commercial milestones and are required to make royalty payments in connection with the sale of products developed under those agreements. The amount and timing of milestone obligations are unknown or uncertain as we are unable to estimate the timing or likelihood of achieving the milestone events. Additionally, the amount of royalty payments are based upon future product sales, which we are unable to predict with certainty. These potential obligations are further described in Note 5 to the financial statements.

Cash flows

The following table summarizes our sources and uses of cash for the periods presented:

	Six Months Ended June 30,	
	2024	**2023**
Net cash used in operating activities	$ (98,858)	$ (68,417)
Net cash provided by investing activities	106,345	9,081
Cash provided by financing activities	1,345	163,285
Net increase in cash and cash equivalents	$ 8,832	$ 103,949

Operating activities

Net cash used in operating activities for the six months ended June 30, 2024 was $98.9 million, consisting of our net loss of $66.8 million, non-cash charges of $84.0 million and net changes in operating assets and liabilities of $52.0 million. Non-cash charges are primarily related to a gain from the sale of our rare pediatric disease PRV of $108.0 million and accretion of discounts on short-term investments of $2.2 million, which was partially offset by share-based compensation expense of $25.7 million. Net changes in operating assets and liabilities are primarily related to an increase in accrued expenses and other current liabilities of $60.5 million and accounts payable of $3.9 million, which was partially offset by an increase in accounts receivable of $9.1 million and prepaid expenses and other current assets of $3.1 million.

Net cash used in operating activities for the six months ended June 30, 2023 was $68.4 million, consisting of our net loss of $88.3 million, non-cash charges of $13.2 million and net changes in operating assets and liabilities of $6.6 million. Non-cash charges is primarily related to share-based compensation expense of $18.9 million, which was partially offset by accretion of discounts on short-term investments of $5.9 million. Net changes in operating assets and liabilities is primarily related to an increase in accounts payable of $4.3 million, an increase in accrued expenses and other current liabilities of $3.6 million and a decrease of deposits and other long-term assets of $0.2 million, which were partially offset by an increase in prepaid expenses and other current assets of $1.3 million and a decrease to operating lease liabilities of $0.2 million.

Investing activities

Net cash provided by investing activities for the six months ended June 30, 2024 was $106.3 million related to the proceeds from the maturity of short-term investments of $184.2 million and from the sale of our rare pediatric disease PRV of $108.0 million, partially offset by the purchase of short-term investments of $168.8 million and acquisition of intangible assets of $17.1 million.

Net cash provided by investing activities for the six months ended June 30, 2023 was $9.1 million related to the proceeds from the maturity of short-term investments of $274.0 million, partially offset by the purchase of short-term investments of $264.7 million and the purchase of property and equipment of $0.2 million.

Financing activities

Cash provided by financing activities for the six months ended June 30, 2024 was $1.3 million related to net proceeds from the issuance of common stock upon stock option exercises and purchases made under our 2021 Employee Stock Purchase Plan.

Net cash provided by financing activities for the six months ended June 30, 2023 was $163.3 million, primarily attributable to the net proceeds from the issuance of common stock in connection with our follow-on offering of common stock of $161.4 million.

Additionally, there was $1.9 million of net cash provided by financing activities related to proceeds from the issuance of common stock upon stock option exercises and purchases made under our 2021 Employee Stock Purchase Plan.

Funding requirements

Since our inception, we have incurred significant operating losses. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future in connection with our ongoing activities.

If our cash, cash equivalents and short-term investments are not sufficient to meet capital needs until such time that we can generate substantial revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. Adequate additional funds may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we may be required to delay, limit, reduce or terminate our research, product development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, stockholder ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect stockholder rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us.

Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions, and disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from inflation, changing interest rates, potential instability in the global banking system, uncertainty with respect to the federal debt ceiling and budget and potential government shutdowns related thereto with respect to the federal budget, global regional conflicts, public health epidemics, or otherwise. Because of the numerous risks and uncertainties associated with product development, we cannot predict the timing or amount of increased expenses and cannot assure that we will ever be profitable or generate positive cash flow from operating activities.

Critical accounting policies and use of estimates

Our critical accounting policies are disclosed in our audited consolidated financial statements for the year ended December 31, 2023, and the related notes, included in our Annual Report.

New Accounting Pronouncements

Refer to Note 2 of the Notes to our Financial Statements included elsewhere in this Quarterly Report on Form 10-Q for a summary of recently issued and adopted accounting pronouncements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

There were no material changes to our market risks from those described in Part II Item 7A. Quantitative and qualitative disclosures about market risk of our 2023 Form 10-K.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of June 30, 2024, management, with the participation of our Principal Executive Officer and Principal Financial Officer, performed an evaluation of the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including the Principal Executive Officer and the Principal Financial Officer, to allow timely decisions regarding required disclosures. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our Principal Executive Officer and Principal Financial Officer concluded that, as of June 30, 2024, our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the six months ended June 30, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II-OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may be involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, in the opinion of management, would have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity and reputational harm, and other factors.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. Before making your decision to invest in shares of our common stock, you should carefully consider the risks and uncertainties described below, together with the other information contained in this quarterly report, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. We cannot assure you that any of the events discussed below will not occur. These events could have a material and adverse impact on our business, financial condition, results of operations and prospects. If that were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment.

Summary of Risk Factors

Our business is subject to several risks and uncertainties, including those immediately following this summary. Some of these risks are:

• We have a limited operating history, have not completed any clinical trials beyond Phase 2, and, to date, have not generated substantial revenue from the sales of our product, OJEMDA, which may make it difficult for investors to evaluate our current business and likelihood of success and viability.

• We have incurred significant net losses since our inception and, to date, have not generated substantial revenue from the sales of our product, OJEMDA. We expect to incur continued losses for the foreseeable future and may never achieve or maintain profitability.

• Our near-term revenues are highly dependent on the successful commercialization of OJEMDA, which received marketing approval in April 2024 from the FDA for the treatment of patients 6 months of age and older with relapsed or refractory pLGG harboring a BRAF fusion or rearrangement, or BRAF V600 mutation. To the extent that OJEMDA is not commercially successful, our business, financial condition and results of operations would be materially and adversely affected and the price of our common stock would decline.

• Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve several objectives relating to the discovery or identification, development and commercialization of OJEMDA and our product candidates.

• We will require substantial additional capital to finance our operations and achieve our goals. If we are unable to raise capital when needed or on terms acceptable to us, we may be forced to delay, reduce or eliminate our research or product development programs, any future commercialization efforts or other operations.

• Clinical trials are very expensive, time-consuming and difficult to design and implement, and involve uncertain outcomes. Furthermore, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials. OJEMDA and our product candidates may not have favorable results in later clinical trials, if any, or receive marketing authorization. If we fail to demonstrate the safety and effectiveness of OJEMDA or our product candidates, our reputation may be harmed and our business will suffer.

• We may rely on data from investigator-initiated studies, as we did for the Phase 1 clinical trial, and we do not control the trial operations or reporting of the results of such trials.

• The development and commercialization of pharmaceutical products are subject to extensive regulation, and we may not obtain marketing authorizations for pimasertib, DAY301 or any future product candidates, on a timely basis or at all.

• The manufacture of pharmaceutical products, including OJEMDA and our product candidates, including pimasertib and DAY301, is complex. Our third-party manufacturers may encounter difficulties in production, which could delay or entirely halt their ability to supply our product candidates for clinical trials or, if approved, our products for commercial sale.

• Our future success depends on our ability to retain our executive officers and key employees and to attract, retain and motivate qualified personnel and manage our human capital.

• We will need to grow the size and capabilities of our organization, and we may experience difficulties in managing this growth.

• If we are unable to obtain and maintain patent protection or other necessary rights for our products and technology, or if the scope of the patent protection obtained is not sufficiently broad or our rights under our patents (owned, co-owned or licensed) is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our products and technology may be adversely affected.

Risks Related to Our Financial Position and Need for Additional Capital

We have a limited operating history, have not completed any clinical trials beyond Phase 2 and, to date, have not generated substantial revenue from the sales of our product OJEMDA, which may make it difficult for investors to evaluate our current business and likelihood of success and viability.

We are a commercial-stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We commenced operations in 2018, and to date, have not generated substantial revenue from the sales of our product, OJEMDA. Investment in drug development is a highly speculative undertaking and involves a substantial degree of risk. To date, we have devoted substantially all of our resources to identifying, acquiring and developing OJEMDA and our product candidates and building our pipeline, organizing and staffing our company, business planning, building a commercial organization, establishing and maintaining our intellectual property portfolio, establishing arrangements with third parties for the manufacture of our product candidates, raising capital and providing selling, general and administrative support for these operations.

Since our inception, we have focused substantially all of our efforts and financial resources on the clinical development of our product, OJEMDA, initially for relapsed or refractory pediatric low-grade gliomas, or pLGGs, and our product candidate, pimasertib, which we are studying in combination with tovorafenib for the treatment of RAS- and RAF-dependent tumors. Further, pursuant to a License Agreement with MabCare Therapeutics, or MabCare, entered into in June 2024, or the MabCare License Agreement, we have exclusive rights to develop, manufacture and commercialize DAY301, a novel ADC targeting PTK7, worldwide, excluding Greater China. To date, we have financed our operations primarily through the sale and issuance of redeemable convertible preferred shares, convertible notes, the completion of our initial public offering, or IPO, and follow-on public offerings of our common stock.

We have not yet demonstrated an ability to successfully complete any clinical trials beyond Phase 2, manufacture a commercial-scale product or arrange for a third party to do so on our behalf or conduct sales and marketing activities necessary for successful product commercialization. As a result, it may be more difficult for you to accurately predict our likelihood of success and viability than it could be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by biopharmaceutical companies in rapidly evolving fields and with recently approved therapies. We also may need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We have not yet demonstrated an ability to successfully overcome such risks and difficulties, or to make such a transition. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

We have incurred significant net losses since our inception and, to date, have not generated substantial revenue from the sales of our product, OJEMDA. We expect to incur continued losses for the foreseeable future and may never achieve or maintain profitability.

We have incurred significant net losses in each reporting period since our inception, have not generated substantial revenue from the sales of our product, OJEMDA, to date and have financed our operations principally through private placements of our redeemable convertible preferred shares, our convertible notes, the completion of our IPO and follow-on offerings of our common stock. For the six months ended June 30, 2024 and 2023, we reported a net loss of $66.8 million and $88.3 million, respectively. We had an accumulated deficit of $525.4 million as of June 30, 2024. We expect to incur increasing levels of operating losses for the foreseeable future, particularly as we advance tovorafenib, pimasertib and DAY301 through clinical development. Our prior losses, combined with expected future losses, have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. We expect our research and development expenses to significantly increase in connection with our additional planned clinical trials for our product and product candidates, including our ongoing pivotal Phase 2 FIREFLY-1 trial for OJEMDA, our ongoing pivotal Phase 3 FIREFLY-2 trial of tovorafenib as a potential front-line therapy in pLGG, our post-marketing commitments and requirements for OJEMDA, our ongoing Phase 1b/2 FIRELIGHT-1 umbrella master trial of tovorafenib in adult RAS/RAF-altered solid tumors as a monotherapy and in combination with pimasertib, our Phase 1/2a trial of DAY301 targeting PTK7 and development of and subsequent Investigational New Drug Applications, or INDs, for any future product candidates we may choose to pursue. In October 2023, the U.S. Food and Drug Administration, or FDA, accepted our New Drug Applications, or NDAs, and granted priority review for OJEMDA as a monotherapy in relapsed or refractory pLGG. On April 23, 2024, the FDA approved the NDAs for OJEMDA for use in the treatment of patients 6 months of age and older with relapsed or refractory pLGG harboring a BRAF fusion or rearrangement, or BRAF V600 mutation. We will incur significant sales, marketing and outsourced manufacturing expenses in connection with the commercialization of OJEMDA, or our product candidates, including pimasertib and DAY301, if marketing

authorization is received. We have also incurred, and will continue to incur, additional costs associated with operating as a public company.

As a result, we expect to continue to incur significant and increasing net losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis. In addition, we expect our financial condition and operating results to fluctuate significantly from quarter-to-quarter and year-to-year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

Our near-term revenues are highly dependent on the successful commercialization of OJEMDA, which received marketing approval in April 2024 from the FDA for the treatment of patients 6 months of age and older with relapsed or refractory pLGG harboring a BRAF fusion or rearrangement, or BRAF V600 mutation. To the extent that OJEMDA is not commercially successful, our business, financial condition and results of operations would be materially and adversely affected and the price of our common stock would decline.

Our future success is highly dependent on our ability to timely complete successful clinical trials, obtain marketing authorization for, and then successfully commercialize, OJEMDA and our product candidates. OJEMDA is our only drug that has been approved for sale and it has only been approved for the treatment of patients 6 months of age and older with relapsed or refractory pLGG harboring a BRAF fusion or rearrangement, or BRAF V600 mutation. Prior to OJEMDA, we have not, as an organization, launched or commercialized a product, and there is no guarantee that we will be able to do so successfully with OJEMDA. There are numerous examples of unsuccessful product launches and failures to meet high expectations of market potential. We are focusing a significant portion of our activities and resources on OJEMDA, and we believe our near-term revenues are highly dependent on, and a meaningful portion of the value of our company relates to, our ability to successfully commercialize OJEMDA in the United States. If the launch or commercialization of OJEMDA is unsuccessful or perceived as disappointing, our stock price could decline significantly and the long-term success of the product and our company could be harmed.

We are early in our development efforts and our product, tovorafenib, is currently in pivotal Phase 3 clinical trials. Our product candidates, pimasertib and DAY301, are in earlier stages of development and are not approved for sale in any jurisdiction. There can be no assurance that tovorafenib, pimasertib, DAY301 or any future product candidates we develop, if any, will achieve success in their clinical trials or obtain marketing authorization.

The success of OJEMDA will depend on several factors, including the following:

• successful and timely completion of current and future clinical trials resulting in attractive, competitive target product profiles, including our pivotal Phase 3 FIREFLY-2 trial of tovorafenib as a front-line therapy for patients with pLGG;

• the results of our ongoing clinical trial for tovorafenib and Phase 1b/2 umbrella master trial of tovorafenib in combination with pimasertib meeting clinical endpoints;

• timely and successful enrollment of patients in, and completion of, clinical trials with favorable results;

• demonstration of safety, effectiveness and acceptable risk-benefit profiles of OJEMDA and our product candidates to the satisfaction of the FDA and foreign regulatory agencies and attractiveness of OJEMDA and our product candidates to physicians, patients, advocates, payors and caregivers;

• our ability, or that of our collaborators, to develop and obtain clearance or approval of complementary or companion diagnostics, if any, on a timely basis, or at all, and an adequate supply of these diagnostics and access to these diagnostics that outpaces demand;

• receipt and related terms of marketing authorizations from applicable regulatory authorities for our product candidates such as pimasertib and DAY301, including potential restrictions or limitations on the conditions of use of our products;

• whether our patents will be sufficient to prevent generic competition for OJEMDA after our orphan drug exclusivity expires;

• the successful completion of any required or committed post-marketing studies and available funding to perform any such post-marketing requirements or post-marketing commitments;

• raising additional funds necessary to complete clinical development and successful commercialization of OJEMDA and our product candidates, including pimasertib and DAY301;

• obtaining and maintaining patent, trade secret and other intellectual property protection and statutory exclusivities for OJEMDA and our product candidates;

• protecting and enforcing our rights in our intellectual property portfolio;

• making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of OJEMDA and our product candidates and ensuring a resilient, effective supply chain that produces supply that outpaces demand;

• developing and implementing marketing, pricing and reimbursement strategies, as well as adequate demand forecasts for supply and sales planning;

• establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others in a market where promotional sales approaches are rapidly moving to digital platforms and access of sales representatives to major institutions remains uncertain;

• acceptance of our products, if and when approved, by patients, physicians, the medical community and third-party payors underpinned by adequate health economic data and a meaningful value proposition;

• obtaining and maintaining third-party payor coverage and adequate reimbursement in both public and private payor spaces across multiple countries;

• effectively competing with other therapies, including those that have not yet entered the market;

• effectively competing with other companies in the pharmaceutical and biotechnology industries, which are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates;

• obtaining appropriate support from patient advocacy organizations;

• effectively shaping the market in the early years following launch to help providers understand a new way of thinking about treating relevant patients;

• addressing any delays in our ongoing and planned clinical trials resulting from factors related to any macroeconomic conditions, major natural disaster, public health epidemic or significant political event, including inflation, changes in interest rates, actual or perceived instability in the global banking system, uncertainty with respect to the federal debt ceiling and budget and potential government shutdowns related thereto and global regional conflicts, as well as any delays due to supply chain issues impacting the availability of certain standard-of-care chemotherapy drugs; and

• maintaining a continued acceptable safety profile of the products following approval.

Many of these factors are beyond our control, and if we cannot address any of them in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize OJEMDA and our product candidates, which would materially harm our business. It is also possible that not all of our product candidates, including pimasertib and DAY301, will obtain marketing authorization even if we expend substantial time and resources seeking such approval.

Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve several objectives relating to the development and commercialization of OJEMDA and our product candidates.

Our business depends entirely on the successful development and commercialization of OJEMDA and our product candidates. Our ability to generate future revenue at the levels or timing we expect and achieve profitability depends on several factors, including, but not limited to, our ability to:

• successfully market and sell OJEMDA while maintaining full compliance with applicable federal and state laws, rules and regulations;

• complete a successful pivotal Phase 3 FIREFLY-2 trial with tovorafenib that achieves a competitive, clinically meaningful and generally well-tolerated target product profile for the front-line treatment of pLGG;

• complete a successful Phase 1b/2 FIRELIGHT-1 umbrella master trial of tovorafenib in combination with pimasertib;

• complete a successful Phase 1/2a trial of DAY301;

• initiate and successfully complete all safety, pharmacokinetic and other studies required to obtain foreign marketing authorization for OJEMDA as a treatment for patients with pLGGs;

• initiate and complete additional, successful late-stage clinical trials that meet their clinical endpoints;

• obtain favorable results from our clinical trials and apply for and obtain marketing authorizations for pimasertib and DAY301 from applicable regulatory authorities, including NDAs from the FDA, and maintaining such approvals;

• establish licenses, collaborations or strategic partnerships that allow for the commercialization of OJEMDA and our product candidates and/or may increase the value of our programs;

• establish and maintain viable supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet the market demand for our product candidates;

• successfully commercialize OJEMDA, pimasertib, and DAY301 and any future product candidates we may develop, if approved, by building and maintaining a sales force and/or entering into collaborations with third parties;

• satisfy any post-marketing requirements imposed by, or post-marketing commitments made to, applicable regulatory authorities, including for OJEMDA;

• demonstrate an acceptable safety profile of our product and our product candidates, including OJEMDA, pimasertib and DAY301, and continue to maintain a continued acceptable safety profile following marketing authorization, if any;

• identify, assess and develop new product candidates;

• establish and maintain patent and trade secret protection, statutory exclusivities and other intellectual property protections for our products;

• obtain, maintain, protect and defend our intellectual property portfolio, including any necessary licenses from third parties;

• address any competing therapies and technological and market developments;

• achieve market acceptance of OJEMDA and our product candidates, including pimasertib and DAY301, if approved, with patients, the medical community and third-party payors, both in the United States and internationally; and

• attract, hire and retain qualified personnel.

To become and remain profitable, we must succeed in developing and commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing clinical trials for OJEMDA and our product candidates, acquiring additional product candidates, establishing arrangements with third parties for the manufacture of clinical supplies of our product candidates, obtaining marketing authorization for our product candidates, obtaining and retaining patents, trade secrets, statutory exclusivities, and other intellectual property protections and marketing and selling products for which we may obtain marketing authorization, if any. We are in the earlier stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

In cases where we are successful in obtaining marketing authorizations to market one or more of our product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain marketing authorizations, the pricing for the product, the duration of treatment with our product, the adoption of our product in treatment guidelines and by prescribers, the ability to obtain coverage and reimbursement and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the approved indication is narrower than expected or the treatment population is narrowed by competition, physician choice, payor decisions or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved.

If we decide to, or are required by the FDA or regulatory authorities in other jurisdictions to, perform studies or clinical trials in addition to those currently expected, or to modify ongoing or planned clinical trials, or if there are any delays in establishing appropriate manufacturing arrangements for, in initiating or completing our current and planned clinical trials for or in the development of, any of our product candidates, our expenses could increase significantly and profitability could be further delayed.

Our failure to become and remain profitable could depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will require substantial additional capital to finance our operations and achieve our goals. If we are unable to raise capital when needed or on terms acceptable to us, we may be forced to delay, reduce or eliminate our research or product development programs, any future commercialization efforts or other operations.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance our product, OJEMDA, and product candidates, pimasertib and DAY301, and any future product candidates through clinical development. We expect increased expenses as we continue our research and development, initiate additional clinical trials, seek to expand our product pipeline, seek marketing authorization for our lead programs and future product candidates, if any, and invest in our organization. In addition, we expect to incur significant expenses related to the product manufacturing, marketing, sales and distribution of OJEMDA and, if we obtain marketing authorization, for our product candidates including pimasertib and DAY301. Furthermore, we have incurred and will continue to incur additional costs associated with operating as a public company, such as acquiring and retaining experienced personnel, developing new information technology systems and other costs associated with being a public company.

Also, we expect to experience ongoing and additional costs related to preparing and filing patent applications, maintaining our intellectual property and potentially expanding our office facilities. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations.

We had $361.9 million in cash, cash equivalents and short-term investments as of June 30, 2024. We believe that our existing cash, cash equivalents and short-term investments, will enable us to fund our operating expenses and capital expenditure requirements into 2026. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Changes beyond our control may occur that would cause us to use our available capital before that time, including changes in and progress of our drug development activities and changes in regulation. Our future capital requirements will depend on many factors, including:

• the progress, timing and results of preclinical studies and clinical trials for our current or any future product candidates;

• the extent to which we develop, in-license or acquire other pipeline product candidates or technologies;

• the number and development requirements of current or future product candidates that we may pursue, and other indications for our current product candidates that we may pursue;

• the costs, timing and outcome of obtaining marketing authorization for our current or future product candidates or the modification of ongoing or planned clinical trials;

• the successful development of and marketing authorization for any complementary or companion diagnostics that may be useful to or necessary for the commercialization of OJEMDA and our product candidates;

• the scope and costs of making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our current or future product candidates;

• the costs involved in growing our organization to the size needed to allow for the research, development and potential commercialization of our current or future product candidates;

• to the extent we pursue strategic collaborations, including collaborations to commercialize OJEMDA, pimasertib, DAY301 or any of our future pipeline products and product candidates, if any, our ability to establish and maintain collaborations on favorable terms, if at all, as well as the timing and amount of any milestone or royalty payments we are required to make or are eligible to receive under such collaborations or our current licenses;

• the cost associated with commercializing any approved products and product candidates, including establishing sales, marketing, market access and distribution capabilities;

• the cost associated with completing any post-marketing studies or trials requested or required by the FDA or other regulatory authorities, including for OJEMDA;

• the revenue, if any, received from commercial sales of OJEMDA, pimasertib, DAY301 or any of our future product candidates, if approved, or any other future pipeline product candidates that receive marketing authorization;

• the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims that we may become subject to, including any litigation costs and the outcome of such litigation; and

• the costs associated with potential product liability claims, including the costs associated with obtaining insurance against such claims and with defending against such claims.

We will require additional capital to complete our planned clinical development programs for our current product candidates to obtain marketing authorization, and we anticipate needing to raise additional capital to complete the development of and to commercialize OJEMDA or our product candidates. Our ability to raise additional funds will depend on financial, economic and market conditions and other factors, over which we may have no or limited control. If adequate funds are not available on commercially acceptable terms when needed, we may be forced to delay, reduce or terminate the development or commercialization of all or part of our research programs or products and product candidates or we may be unable to take advantage of future business opportunities. Furthermore, any additional capital-raising efforts may divert our team’s attention from their day-to-day activities, which may adversely affect our business, including our ability to develop and commercialize our current and future product candidates, if approved. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

We will be required to obtain further funding through public or private equity financings, debt financings, collaborative agreements, licensing arrangements or other sources of financing, which may dilute our stockholders or restrict our operating activities. We do not have any committed external source of funds. We have entered into an equity distribution agreement, or the Equity Distribution Agreement, with Piper Sandler & Co. and JonesTrading Institutional Services LLC, as sales agents, relating to the issuance and sale of shares of our common stock for an aggregate offering price of up to $250.0 million under an at-the-market offering program, or the

ATM. No shares of our common stock have been sold under the ATM as of June 30, 2024. To the extent that we raise additional capital through the sale of equity or convertible debt securities, including pursuant to the ATM, each investor's ownership interests will be diluted, and the terms may include liquidation or other preferences that adversely affect each investor's rights as a stockholder. Debt financing may result in imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through upfront payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to our product candidates or grant licenses on terms that are not favorable to us. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from inflation, changes in interest rates, actual or perceived instability in the global banking system, uncertainty with respect to the federal debt ceiling and budget and potential government shutdowns related thereto, global regional conflicts, public health epidemics or otherwise.

Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research or drug development programs, clinical trials or future commercialization efforts.

Risks Related to Development and Commercialization of OJEMDA and our Product Candidates

Clinical trials are very expensive, time-consuming and difficult to design and implement, and involve uncertain outcomes. Furthermore, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials. OJEMDA and our product candidates may not have favorable results in later clinical trials, if any, and not all of our product candidates will receive marketing authorization. If we fail to demonstrate the safety and effectiveness of OJEMDA and our product candidates, our reputation may be harmed and our business will suffer.

The risk of failure for OJEMDA and our product candidates is high. It is impossible to predict when or if OJEMDA and our product candidates will prove effective or safe in humans or if our product candidates will receive marketing authorization. To obtain the requisite marketing authorizations to market and sell our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans for use in each target indication. Clinical testing is expensive and can take many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the clinical trial process.

In addition, the results of preclinical studies and earlier clinical trials may not be predictive of the results of later-stage preclinical studies or clinical trials. We have limited clinical data for OJEMDA and our product candidates. Products and product candidates in later stages of clinical trials may fail to show similar or desired safety and efficacy traits despite having progressed through preclinical and earlier stage clinical trials.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product or product candidate due to numerous factors, including changes in clinical trial procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the dosing regimen and other clinical trial protocols and the rate of discontinuation among clinical trial participants.

If we fail to produce positive results in our planned clinical trials of any of our product candidates, the development timeline and marketing authorization and commercialization prospects for our product candidates, and, correspondingly, our business and financial prospects, would be materially and adversely affected.

OJEMDA has only been studied in a limited number of patients. Following commercial launch, OJEMDA will be available to a much larger number of patients, and we do not know whether the results of OJEMDA's use in such larger number of patients will be consistent with the results from our clinical studies.

OJEMDA has been administered only to a limited number of patients in clinical studies. While the FDA granted accelerated approval of OJEMDA based on the data included in the NDAs, we do not know whether the real world safety and effectiveness of the product will be consistent with the safety and effectiveness profile seen in the clinical studies. New data relating to OJEMDA, including from adverse events reports and our post-marketing commitments in the United States, and from other ongoing clinical studies, may result in changes to the product label and may adversely affect sales, or result in withdrawal of OJEMDA from the market. If any of these actions were to occur, it could result in significant expense and delay and/or limit our ability to generate future sales revenues in line with our expectations.

We may rely on data from investigator-initiated studies, as we did for the Phase 1 clinical trial, and we do not control the trial operations or reporting of the results of such trials.

From time to time, we may rely on certain clinical data from investigator-sponsored clinical studies, and we do not control the trial operations or reporting of the results of such trials. This was the case for the initial Phase 1 study for our product, OJEMDA, which was run as an investigator-initiated, multi-center trial in patients with relapsed or refractory pLGG that is being conducted by the Dana

Farber Cancer Institute in collaboration with the Pacific Pediatric Neuro-Oncology Consortium, or PNOC. The last data reported from that trial was in January 2023. It is possible that additional data, when reported, will not demonstrate similar results. We have no control over the timing of such clinical data announcements. Our pivotal Phase 2 FIREFLY-1 trial OJEMDA is a Day One-sponsored trial. In addition, in later-stage clinical trials, we will likely be subject to more rigorous statistical analyses than in completed earlier stage clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in later-stage clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials, and we cannot be certain that we will not face similar setbacks. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing authorization for their product candidates.

Furthermore, we do not control the design or administration of investigator-sponsored trials, nor the submission or approval of any IND or foreign equivalent required to conduct these trials, and the investigator-sponsored trials could, depending on the actions of such third parties, jeopardize the validity of the clinical data generated, identify significant concerns with respect to our product candidates that could impact our findings or clinical trials and adversely affect our ability to obtain marketing authorization from the FDA or other applicable regulatory authorities. To the extent the results of this or other investigator-sponsored trials are inconsistent with, or different from, the results of our planned company-sponsored trials or raise concerns regarding our product candidates, the FDA or a foreign regulatory authority may question the results of the company-sponsored trial or subject such results to greater scrutiny than it otherwise would. In these circumstances, the FDA or such foreign regulatory authorities may require us to obtain and submit additional clinical data, which could delay clinical development or marketing authorization of our product candidates. While investigator-sponsored trials could be useful to inform our own clinical development efforts, we do not control the data or timing of data releases for investigator-sponsored trials, and there is no guarantee that we will be able to use the data from these trials to form the basis for marketing authorization of our product candidates.

Our compassionate use programs could subject us to additional risks, including delays in our clinical trial programs, impacts to our supply capabilities, or adverse publicity.

Some patients receive access to investigational drugs outside of clinical trials through compassionate use programs, which refer to expanded access or right to try programs. These patients generally have life-threatening illnesses for which there are no alternative therapies or they have exhausted all other available therapies. There are a number of risks that we may face as a result of our compassionate use programs. For example, the risk for serious adverse events in this patient population is high, which, if those adverse events are determined to be drug-related, could have a negative impact on the safety profile of our drug candidates and/or cause significant delays, result in an inability to successfully commercialize our drug candidates and/or materially harm our business. Additionally, if we were to provide patients with any of our drug candidates under a compassionate use program, our supply capabilities may limit the number of patients who are able to enroll in the program. It also may become challenging to enroll patients in randomized trials if product candidates are being supplied to patients under expanded access programs. These factors may result in the need to restructure or pause any compassionate use program in order to enroll sufficient numbers of patients in our clinical trials required for marketing authorization and successful commercialization of our drug candidates. If we were to restructure or pause our compassionate use programs, we could face adverse publicity or disruptions related to current or potential participants in our programs.

Our clinical trials may be suspended, delayed or fail to adequately demonstrate the safety and effectiveness of OJEMDA and our product candidates, which would prevent or delay development, marketing authorization and commercialization.

Before obtaining marketing authorization from the FDA or comparable foreign regulatory authorities for the sale of OJEMDA and our product candidates, we must demonstrate through lengthy, complex and expensive clinical trials that our product candidates are both safe and effective for use in each target indication. Clinical testing is expensive, difficult to design and implement, can take many years to complete and its ultimate outcome is uncertain. Failure can occur at any time during the clinical trial processes and for any number of reasons, and, because our product candidates are in earlier stages of development, there is a high risk of failure and we may never succeed in developing marketable products.

We may experience numerous challenges and unforeseen events during, or as a result of, clinical trials that could delay or prevent receipt of marketing authorization or our ability to successfully commercialize OJEMDA or our product candidates, including:

- the FDA or other regulators refusing to permit our clinical studies to proceed or placing studies on hold before or after the studies begin;
- a failure to demonstrate that the dose for a product candidate has been optimized;
- failure of our product candidates in clinical trials to demonstrate important functional, quality, or patient-reported outcomes;
- changes in the competitive landscape causing clinical trial enrollment challenges or preventing or delaying marketing authorization in one or several subsets studied in our programs, including in relapsed or front-line pLGG;

• receipt of feedback from regulatory authorities that requires us to modify the design of our clinical trials;

• negative or inconclusive clinical trial results that may require us to conduct additional clinical trials or abandon certain research and/or drug development programs;

• the number of patients required for clinical trials being larger than anticipated, enrollment in these clinical trials being slower than anticipated or participants dropping out of these clinical trials at a higher rate than anticipated;

• unanticipated delays in our preclinical studies or clinical trials;

• third-party contractors failing to comply with regulatory requirements, including Good Clinical Practice, or GCP, regulations, or meet their contractual obligations to us in a timely manner, or at all;

• the suspension or termination of our clinical trials for various reasons, including non-compliance with regulatory requirements or a finding that our product candidates have undesirable side effects or other unexpected characteristics or risks;

• the cost of clinical trials of our product candidates being greater than anticipated;

• the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates being insufficient or inadequate;

• failure of our clinical trials to demonstrate the safety or effectiveness of our product candidates;

• regulators revising the requirements for approving our product candidates; and

• receipt of feedback from regulatory authorities that would require us to include data from additional patients or longer term efficacy and safety data.

We may also face unanticipated regulatory hurdles in our drug development program that may require additional data generation or delay our existing or planned trials and the timing of applications for marketing authorization. For instance, we may make formulation or manufacturing changes to our product candidates, in which case we may need to conduct additional preclinical studies to bridge our modified product candidates to earlier versions. Additionally, the FDA may determine that it has questions or concerns about our trials and may not permit our proposed clinical studies to move forward by imposing a partial or full clinical hold.

Further, we, the FDA or an institutional review board, or IRB, may suspend our clinical trials at any time if it appears that we or our collaborators are failing to conduct a trial in accordance with regulatory requirements, including GCP regulations, that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our INDs or the conduct of these trials. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials.

We may also conduct clinical trials in foreign countries, which presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries. Further, data from trials conducted outside of the United States may be subject to additional scrutiny by the FDA, which may require that additional U.S. data be generated.

Because some of our product candidates are targeted towards the pediatric population, we may face additional hurdles and be subjected to greater scrutiny by regulatory agencies. Trials involving pediatric populations can be difficult to conduct, can be quite costly and, like other clinical trials, may not yield the anticipated results. In addition, pediatric studies are more dependent on a smaller number of specialized clinical trial sites, which in turn can limit site availability and make the trials more expensive to conduct. In addition, as interest in pediatric indications grows as a result of the Research to Accelerate Cures and Equity (RACE) for Children Act and other market forces, trial recruitment may become even more difficult due to competition for eligible patients. Moreover, it may be challenging to ensure that pediatric or adolescent patients adhere to clinical trial protocols. Our inability to enroll a sufficient number of pediatric patients for our clinical trial could result in significant delays, require us to abandon one or more clinical trials altogether, impact our ability to raise additional capital and delay or prevent our ability to obtain necessary marketing authorizations for any drug product candidate.

We cannot predict the outcome of our clinical trials, nor can we guarantee that the data we generate from our clinical trials will be acceptable to regulatory authorities so as to support marketing authorization.

The outcome of clinical trials is uncertain, and, because our product candidates are in earlier stages of development, there is a significant risk of failure. If we complete our clinical trials but the results of our clinical trials are inconclusive or only modestly positive, if there are safety concerns or serious adverse events associated with our product candidates or if our clinical trials are delayed or require unplanned changes, we may:

• incur additional, unplanned drug development and/or commercialization costs;

• be delayed in obtaining or unable to obtain marketing authorization;

• be required to perform additional clinical trials to support approval;

• obtain approval for indications or patient populations that are not as broad as intended or desired or may have contraindications, limitations of use or other restrictions that affect the market for the product;

• obtain marketing authorization with labeling that includes safety warnings, a risk evaluation and mitigation strategy, or REMS, and/or other restrictions on distribution or use that could affect market access;

• be subject to additional post-marketing testing requirements or commitments;

• have regulatory authorities withdraw, or suspend, their approval of the drug or impose post-marketing safety labeling changes or a REMS;

• be subject to civil or criminal investigations and litigation; or

• experience damage to our reputation.

If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be negatively impacted, and our ability to generate revenues from our product candidates may be delayed or eliminated entirely.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or a comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or has affected the conduct or interpretation of the study. The FDA or a comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing authorization of one or more of our product candidates.

If we experience delays or difficulties in enrolling patients in our ongoing or planned clinical trials, we may be delayed in or prevented from obtaining necessary marketing authorization for any or all of our product candidates.

We may not be able to initiate or continue our ongoing or planned clinical trials for our product candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or comparable foreign regulatory authorities. In our OJEMDA program, we utilize genomic profiling of patients' tumors to identify suitable patients for recruitment into our clinical trials. We cannot be certain (i) how many patients will have the requisite alterations for inclusion in our clinical trials, (ii) that the number of patients enrolled in each program will suffice for marketing authorization or (iii) whether each specific BRAF mutation targeted will be included in the approved drug labeling. If our strategies for patient identification and enrollment prove unsuccessful, we may have difficulty enrolling or maintaining patients appropriate for our product candidates. Patient enrollment is also affected by other factors, including:

• severity of the disease under investigation;

• our ability to recruit clinical trial investigators of appropriate competencies and experience;

• the incidence and prevalence of our target indications;

• clinicians' and patients' awareness of, and perceptions as to, the potential advantages and risks of our product candidates in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;

• the availability, expertise and selection of contract research organizations, or CROs, to manage operations related to clinical trial enrollment;

• competing studies or trials with similar eligibility criteria;

• any invasive procedures that may be required to enroll patients and to obtain evidence of the product candidate's performance during the clinical trial;

• availability and efficacy of approved medications for the disease under investigation;

• ongoing shortages of chemotherapy standard of care, which may be used in the control arm of certain of our clinical trials, including FIREFLY-2 and our Phase 1/2a trial for DAY301;

• eligibility criteria defined in the protocol for the trial in question;

• the size and nature of the patient population required for analysis of the trial's primary endpoints;

• efforts to facilitate timely enrollment in clinical trials;

• whether we are subject to a partial or full clinical hold on any of our clinical trials;

• reluctance of physicians or patient advocacy organizations to encourage patient participation in clinical trials;

• the ability to monitor patients adequately during and after treatment;

• our ability to obtain and maintain patient consents; and

• proximity and availability of clinical trial sites for prospective patients.

In addition, the conditions for which we currently plan to evaluate our product candidates are orphan or rare diseases with limited patient pools from which to draw for clinical trials. The eligibility criteria of our clinical trials, once established, will further limit the pool of available trial participants. Further, some of our competitors currently have ongoing clinical trials for product candidates that would treat the same patients as our clinical product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. Moreover, if any of our competitors receive FDA approval for a product, it may limit our ability to enroll patients in our clinical trials if they decide to seek treatment with an approved product. For example, in March 2023, Novartis received approval for dabrafenib in combination with trametinib, which could in the future limit our ability to enroll patients in clinical trials for OJEMDA.

Our inability to enroll and maintain a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials or clinical programs altogether. There may be competing trials, as well as the limited bandwidth of pediatric oncology institutions for running trials, which can lead to the prioritization of certain trials, resulting in delays in our clinical trials. In addition, because our product candidates are initially targeted to pediatric populations, we may face additional challenges. For example, parents may be reluctant to enroll their children in our clinical trials or may decide to withdraw their children from our clinical trials to pursue other therapies.

Preliminary, interim, initial and topline data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary, interim or topline data from our clinical trials. These updates are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study. Additionally, interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Therefore, positive interim or initial results in any ongoing clinical trial may not be predictive of such results in the completed study. Initial or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. For example, our FIREFLY-1 clinical trial was designed to use the Response Assessment for Neuro-Oncology – High Grade Glioma, or RANO-HGG, to measure the primary endpoint of overall response rate, or ORR, in alignment with the FDA, with ORR using Response Assessment for Pediatric Neuro-Oncology – Low-Grade Glioma, or RAPNO-LGG, as a secondary endpoint. Following discussions with the FDA and the March 2023 approval of dabrafenib, in combination with trametinib in BRAF V600E pLGG, we initially structured the primary endpoint in our FIREFLY-2/LOGGIC trial to be assessed using the Response Assessment for Neuro-Oncology Low-Grade Glioma, or RANO-LGG, and have included RANO-LGG as an exploratory endpoint in FIREFLY-1. Following further feedback from the FDA during review of the NDAs for OJEMDA, in June 2024 we updated the structure of the primary endpoint in our FIREFLY-2/LOGGIC trial to be assessed using the Response Assessment in Pediatric Neuro-Oncology Low-Grade Glioma, or RAPNO-LGG, criteria.

In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, drug candidate or our business. If the topline data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

We face substantial competition which may result in others discovering, developing or commercializing products before or more successfully than we do.

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates. Our competitors have developed, are developing or may develop products, product candidates and processes competitive with our product candidates. Any products or product candidates that we successfully develop and commercialize, including OJEMDA, may compete with existing therapies and new therapies that may become available in the future. We believe that a significant number of competing product candidates are currently under development, and may become commercially available in the future, for the treatment of conditions for which we are developing, or may in the future develop, product candidates. In addition, our product candidates may need to compete with drugs that are prescribed off-label to treat the indications for which we seek approval. This may make it difficult for us to replace existing therapies with our product candidates.

We also compete with these organizations to recruit and retain qualified scientific, management and sales and commercial and marketing personnel, which could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

In particular, there is intense competition in the field of oncology. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, emerging and start-up companies, universities and other research institutions.

We expect to face competition from existing products and products in development for each of our programs. Drug discovery efforts focused on V600 mutations have led to clinical success in some cancers. Three BRAF inhibitors have been approved by the FDA for the treatment of tumors containing V600E or V600K mutations. These first-generation BRAF inhibitors, known more generally as Type I RAF inhibitors, are vemurafenib, marketed as Zelboraf® by Genentech; dabrafenib, marketed as Tafinlar® by Novartis; and encorafenib, marketed as Braftovi® by Pfizer. Dabrafenib, in combination with trametinib, marketed as Mekinist® by Novartis, has been approved for the treatment of adult and pediatric patients ≥ 6 years of age with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options. This includes BRAF V600E pLGG, a subset of the greater RAF-altered pLGG clinical scope of the OJEMDA development program. We believe that current data indicates that the BRAF V600E subset represents 10%-20% of BRAF-altered pLGG, but additional epidemiologic data may emerge as more patients are profiled. Further, dabrafenib, in combination with trametinib, was granted full approval in the BRAF V600E pLGG indication in March 2023 to include the treatment of pediatric patients 1 year of age and older with low-grade glioma, or LGG, with a BRAF V600E mutation who require initial systemic therapy.

Four MEK inhibitors have been approved by the FDA. Three have been approved for the treatment of tumors containing BRAF V600E or V600K mutations, including cobimetinib, marketed as Cotellic® by Genentech; trametinib, marketed as Mekinist® by Novartis; and binimetinib, marketed as Mektovi® by Pfizer. A fourth MEK inhibitor—selumetinib, marketed as Koselugo® by AstraZeneca—has been approved for the treatment of pediatric patients two years of age and older with neurofibromatosis type 1, or NF1, who have symptomatic, inoperable plexiform neurofibromas. While MEK inhibitors as monotherapy have been shown to be active in BRAF altered pLGG (both BRAF V600E mutant pLGG and BRAF fusion-driven pLGG), no MEK inhibitors have been approved by the FDA as a monotherapy for the treatment of patients with pLGG.

There are a number of next-generation BRAF inhibitors in clinical development. BeiGene has two next-generation BRAF programs: Lifirafenib (BGB-283), which is currently in a Phase 1/2 trial in combination with mirdametinib, and BGB-3245 which is currently in a single agent in Phase 1 dose escalation study. Fore Therapeutics (formerly NovellusDx) is developing the RAF dimer breaker PLX8394 in a Phase 1/2 trial in combination with cobicistat. Black Diamond Therapeutics have next-generation BRAF inhibitors in Phase 1 clinical trials. Jazz Pharmaceuticals and Redx have announced that the pan-RAF inhibitor JZP815 has entered clinical development in a Phase 1 trial. Erasca recently announced that it has entered into an exclusive worldwide license agreement with Novartis for naporafenib, a Phase 3 pivotal-ready pan-RAF inhibitor with a potential first-in-class and best-in-class profile in NRAS mutant melanoma and other RAS/MAPK pathway-driven tumors. Nested Therapeutics has advanced NST-628, a pan-RAF/MEK “molecular glue” into a Phase 1 clinical trial.

With regard to the treatment of pLGG, some MEK inhibitors, some type I RAF inhibitors, and other targeted therapies have been studied, or are being studied, in academic investigator-initiated clinical trials, and in some regions may be being used in an off-label manner. The off-label use of these agents may represent competition for OJEMDA if it is approved and enters the market.

Further, pursuant to the MabCare License Agreement, we have the exclusive right to develop, manufacture and commercialize DAY301, a novel ADC targeting PTK7, worldwide, excluding Greater China. We expect the first patient to be dosed in the Phase I study for DAY301 in the fourth quarter of 2024 or first quarter of 2025. In February 2024, Profound Bio has dosed its first patient in a Phase 1/2 Clinical Trial of PRO1107, a PTK7-targeted antibody-drug conjugate.

Many of our competitors, either alone or with their collaborators, have significantly greater financial resources, established presence in the market and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining marketing authorizations and reimbursement and marketing approved products than we do.

Large pharmaceutical and biotechnology companies, in particular, have extensive experience in clinical testing, obtaining marketing authorizations, recruiting patients and manufacturing biotechnology product candidates. These companies also have significantly greater research, marketing and sales capabilities than we do and may also have product candidates that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical and biotechnology companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies, as well as in acquiring technologies complementary to, or necessary for, our programs.

As a result of all of these factors, our competitors may succeed in obtaining approval from the FDA or comparable foreign regulatory authorities or in discovering, developing and commercializing product candidates in our field before we do, which could result in our competitors establishing a strong market position before we are able to enter the market with a particular product or product candidate or could make our development more complicated.

Our potential commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, have a broader label, are marketed more effectively, are more widely reimbursed or are less expensive than OJEMDA or our other product candidates. Even if the product candidates we develop achieve marketing authorization, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical. If we are unable to compete effectively, our opportunity to generate future revenue from the sale of the product candidates we may develop, if approved, could be adversely affected.

Safety risks or other side effects associated with OJEMDA, pimasertib, DAY301 or any future products and product candidates we may develop could delay or preclude approval, cause us to suspend or discontinue clinical trials or abandon further development, limit the use of an approved product or result in significant negative consequences following marketing authorization, if any.

As is the case with pharmaceuticals generally, we have observed side effects and adverse events associated with our product, OJEMDA, and our product candidates. The most common side effects (adverse events) observed to date with OJEMDA included maculopapular rash, anemia, headache, elevation in blood creatinine phosphokinase, or CPK, nausea, skin and hair discoloration and fatigue.

Results of our ongoing and planned clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. These side effects or unexpected characteristics may be subject to regulatory reporting requirements before and/or after approval. Undesirable side effects caused by OJEMDA or our product candidates could result in the delay, suspension or termination of clinical trials by us or regulatory authorities for a number of reasons. Furthermore, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of subjects and limited duration of exposure, rare and severe side effects of OJEMDA or our product candidates or those of our competitors may only be uncovered with a significantly larger number of patients exposed to the drug.

Additionally, patients treated with OJEMDA and our product candidates have undergone, or may also be undergoing, medical, surgical, radiation and chemotherapy treatments, which can cause side effects or adverse events that are unrelated to OJEMDA or our product candidates but may still impact the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses. For example, it is expected that some of the patients to be enrolled in our future clinical trials will die or experience major clinical events either during the course of our clinical trials or after participating in such trials for non-treatment related reasons, which could impact development of OJEMDA, pimasertib, DAY301 or our other product candidates. If we elect or are required to delay, suspend or terminate any clinical trial, the commercial prospects of OJEMDA and our product candidates will be harmed and our ability to generate product revenues from such product or product candidate will be delayed or eliminated. Serious adverse events, or SAEs, observed in clinical trials could hinder or prevent market acceptance of any approved products or reduce the duration of time that physicians expect to use our product in particular patients. Any of these occurrences may significantly harm our business, prospects, financial condition and results of operations.

Moreover, if OJEMDA or our product candidates are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may elect to abandon or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for our product candidates, if approved. We may also be required to modify our study plans based on findings in our clinical trials. Such side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial. Many drugs that initially showed promise in early-stage testing have later been found to cause side effects that

prevented further development. In addition, regulatory authorities may draw different conclusions, require additional testing to confirm these determinations, require more restrictive labeling or deny marketing authorization of the product candidate.

It is possible that, as we test OJEMDA or our product candidates in larger, longer and more extensive clinical trials, including with different dosing regimens, or as the use of our product candidates becomes more widespread following any marketing authorization, illnesses, injuries, discomforts and other adverse events that were observed, did not occur or went undetected in earlier trials, will be reported by patients. If such side effects become known later in development or upon approval, if any, such findings may significantly harm our business, financial condition, results of operations and prospects.

If any of our product candidates receive marketing authorization, and we or others later identify undesirable side effects caused by treatment with such drug, a number of potentially significant negative consequences could result, including:

• regulatory authorities may withdraw approval of the drug;

• we may be required to recall a product or change the way the drug is administered to patients;

• regulatory authorities may require additional warnings in the labeling, such as a contraindication or a boxed warning, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;

• we may be required to implement a REMS or create a medication guide outlining the risks of such side effects for distribution to patients;

• regulatory authorities may impose additional restrictions on the marketing or promotion of the particular product or the manufacturing processes for the product or any component thereof;

• we could be sued and held liable for harm caused to patients;

• we may be subject to regulatory investigations and government enforcement actions;

• the drug could become less competitive; and

• our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market authorization or acceptance of our product candidates, if approved, and could significantly harm our business, financial condition, results of operations and prospects.

We may expend our limited resources to pursue a particular product or product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and products and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and products and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

The market opportunities for any products and product candidates we develop, if approved, may be limited to certain smaller patient subsets and may be smaller than we estimate them to be.

On April 23, 2024, the FDA approved the NDAs for the treatment of patients 6 months of age and older with relapsed or refractory pLGG harboring a BRAF fusion or rearrangement, or BRAF V600 mutation. We have commenced the commercial launch of OJEMDA in the United States. There is no guarantee that OJEMDA or our product candidates will be approved for the front-line setting, and prior to any such approvals we may have to conduct additional clinical trials that may be costly, time-consuming and subject to risk.

Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers in a position to receive a particular line of therapy and who have the potential to benefit from treatment with OJEMDA and our product candidates, are based on our beliefs and estimates. For example, pLGG is a rare disease, and our projections of both the number of people who have this disease, as well as the subset of people with pLGG who have the potential to benefit from treatment with OJEMDA and our product candidates, are based on estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations and market research. These estimates may prove to be incorrect. Additionally, new studies or information may change the estimated incidence or prevalence of the cancers that we are targeting, which could affect our eligibility for orphan designation for certain indications. The potentially addressable patient population for OJEMDA

and our product candidates may be limited or may not be amenable to treatment with OJEMDA and our product candidates. Consequently, even if our product candidates are approved, the number of patients that may be eligible for treatment with our product candidates may turn out to be much lower than expected. Even if we obtain significant market share for our products, if the potential target populations are small, we may never achieve profitability without obtaining marketing authorization for additional indications, if at all.

Our clinical development activities are primarily focused on the development of targeted therapeutics for patients with genomically-defined cancers, which is a rapidly evolving area of science, and the approach we are taking to discover and develop drugs is novel and may never lead to additional approved or marketable products.

The discovery and development of targeted therapeutics for patients with genomically-defined cancers is an emerging field, and the scientific discoveries that form the basis for our efforts to discover, identify and develop product candidates are relatively new. The scientific evidence to support the feasibility of developing product candidates based on these discoveries is both preliminary and limited. Although we believe, based on our products and product candidates' preclinical trial results and our clinical work, that the genomic alterations targeted by our programs are oncogenic drivers, clinical results may not confirm this hypothesis or may only confirm it for certain alterations or certain tumor types. The patient populations for OJEMDA and our product candidates are limited to those with specific target alterations and may not be completely defined but are substantially smaller than the general treated cancer population. In some cases, the target patient populations may not be completely defined. We will need to screen and identify appropriate patients with the targeted alterations. Successful identification of patients is dependent on several factors, including achieving certainty as to how specific alterations respond to OJEMDA and our product candidates and the ability to identify such alterations. Furthermore, even if we are successful in identifying patients, we cannot be certain that the resulting patient populations for each mutation will be large enough to allow us to successfully obtain approval for each mutation type and successfully commercialize OJEMDA and our product candidates and achieve profitability. In addition, even if our approach is successful in showing clinical benefit for RAF-driven cancers for our OJEMDA program, we may never successfully identify additional oncogenic alterations sensitive to OJEMDA in other MAPK-driven tumors. Therefore, we do not know if our approach of treating patients with genomically-defined cancers will be successful, and if our approach is unsuccessful, our business will suffer.

OJEMDA and our product candidates, including pimasertib and DAY301, may not achieve adequate market acceptance among physicians, healthcare professionals, patients or their families, healthcare payors and others in the medical community necessary for commercial success.

Our product, OJEMDA, and product candidates, including pimasertib and DAY301, if approved, may not achieve adequate market acceptance among physicians, healthcare professionals, patients or their families, healthcare payors and others in the medical community necessary for commercial success. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the efficacy, durability and safety profile as demonstrated in clinical trials compared to alternative treatments, in addition to functional, quality or patient-reported outcomes;
- the timing of market introduction of the product candidate and of any competitive products;
- the clinical indications for which a product candidate is approved;
- restrictions on the use of product candidates in the labeling approved by regulatory authorities, such as boxed warnings or contraindications in labeling, or REMS, which may not be required of alternative treatments and competitor products;
- the potential and perceived advantages of OJEMDA and our product candidates over alternative treatments;
- the cost of treatment in relation to alternative treatments and the cost/benefit ratios of each;
- the availability of coverage and adequate reimbursement by third-party payors, including government authorities, and timing of relevant formulary decision-making resulting in this coverage and reimbursement;
- relative convenience and ease of administration in relation to competition;
- the willingness of the target patient population (which may include willingness of our pediatric patients' parents) to try new therapies and undergo required diagnostic screening to determine treatment eligibility and of physicians to prescribe these therapies and diagnostic tests;
- the effectiveness of sales and marketing efforts and market access;
- unfavorable publicity relating to our product candidates; and
- the approval of other new therapies for the same indications.

If our product candidates are approved but do not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate or derive sufficient revenue from that product candidate and our financial results could be negatively impacted. With respect to OJEMDA specifically, successful commercialization will depend on negotiations with, and coverage, reimbursement, selection and/or acquisition decisions by, third-party payors, which we cannot predict. These decisions in turn may depend on value assessments conducted by various entities (e.g., formulary committees, such as pharmacy and therapeutics committees, healthcare systems and pharmacies, among others) that consider various factors (including the price of OJEMDA)—the outcomes of which we cannot predict.

Any products and product candidates we develop may become subject to unfavorable third-party coverage and reimbursement practices, as well as price restrictions.

The availability and extent of coverage and adequate reimbursement by third-party payors, including government health administration authorities, private health coverage insurers, managed care organizations and other third-party payors is essential for most patients to be able to afford expensive treatments. Sales of any of our products, including OJEMDA, and our product candidates, including pimasertib and DAY301, should it receive marketing authorization, will depend substantially, both in the United States and internationally, on the extent to which the costs of such products and product candidates will be covered and reimbursed by third-party payors, as patients who are prescribed medicine for the treatment of their condition generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Further, coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize OJEMDA and product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our investment. Coverage and reimbursement may impact the demand for, or the price of, any product or product candidate for which we obtain marketing authorization.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products, particularly pediatric products. The payor mix for pediatric products in the United States is a fragmented combination of state-specific Medicaid policies and a broad universe of private insurance companies. There is no consistent policy or leading payor to inform other price-setting entities. Public and private payor policies are expected to be critical to our ability to achieve broad payment coverage. Further, to the extent one or more of our products obtain coverage by one third-party payor, that does not assure that other payors will also provide coverage for the product. As a result, the coverage determination process is often time-consuming and costly. This process will require us to provide scientific and clinical support for the use of our products to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

As federal and state governments implement additional health care cost containment measures, including measures to lower prescription drug pricing, we cannot be sure that our products, if approved, will be covered by private or public payors, and if covered, whether the reimbursement will be adequate or competitive with other marketed products. These and other actions by federal and state governments and health plans may put additional downward pressure on pharmaceutical pricing and health care costs, which could negatively impact coverage and reimbursement for our products (if approved), our revenue and our ability to compete with other marketed products and to recoup the costs of our research and development.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are generally challenging the prices for medical products, including by examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific products on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We plan to conduct pharmaco-economic studies to demonstrate the medical necessity and cost-effectiveness of our products, which may be costly. Nonetheless, our products and product candidates may not be considered medically necessary or cost-effective. Moreover, third-party payor coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be.

In addition, complementary and companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for related pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics. Additionally, if any companion diagnostic provider is unable to obtain reimbursement or is inadequately reimbursed, that may limit the availability of such companion diagnostic, which would negatively impact prescriptions for our product candidates, if approved.

Outside the United States, the commercialization of therapeutics is generally subject to extensive governmental price controls and other market regulations. We believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates. In many countries, particularly the countries of the European Union, or EU, medicinal product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after

a product receives marketing authorization. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In general, product prices under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive marketing authorization, less favorable coverage policies and reimbursement rates may be implemented in the future.

If we are unable to establish or sustain coverage and adequate reimbursement for any products from third-party payors, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product, if approved.

Our business entails a significant risk of product liability and if we are unable to obtain sufficient insurance coverage such inability could have an adverse effect on our business and financial condition.

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing and commercialization of OJEMDA and any future products and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA or other regulatory authority investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs. The FDA or other regulatory authority investigations could potentially lead to a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time, our resources and substantial monetary awards to trial participants or patients. We currently have product liability insurance that we believe is appropriate for our stage of development and may need to obtain higher levels prior to advancing our product candidates into clinical trials or marketing any of our product candidates, if approved. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have an adverse effect on our business and financial condition.

Risks Related to Government Regulation

The development and commercialization of pharmaceutical products are subject to extensive regulation, and we may not obtain marketing authorizations for pimasertib, DAY301 or any future product candidates, on a timely basis or at all.

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, import, marketing, distribution, adverse event reporting, including the submission of safety and other post-marketing information and reports, and other possible activities relating to OJEMDA and pimasertib and DAY301, currently our only product and product candidates in planned or ongoing clinical trials, as well as any other product candidate that we may develop in the future, are subject to extensive regulation. Marketing authorization of drugs in the United States requires the submission of an NDA to the FDA. An NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding pharmacology, chemistry, manufacturing and controls. We are not permitted to market any product candidate in the United States until we obtain approval from the FDA of the NDA for that product.

The FDA may refer any application we submit to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, which reviews, evaluates and provides advice and recommendations to the FDA as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

FDA approval of an NDA is not guaranteed, and the review and approval process is an expensive and uncertain process over which the FDA has substantial discretion. The FDA approval process may also take several years. The number and types of preclinical studies and clinical trials that will be required for NDA approval vary depending on the product candidate, the disease or the condition that the product candidate is designed to treat and the regulations applicable to any particular product candidate. Of the large number of drugs in development in the United States, only a small percentage will successfully complete the FDA marketing authorization process and will be commercialized. On April 23, 2024, the FDA approved the NDAs for the treatment of patients 6 months of age and older with relapsed or refractory pLGG harboring a BRAF fusion or rearrangement, or BRAF V600 mutation. In connection with its approval of OJEMDA, the FDA may impose restrictions, post-marketing requirements or post-marketing commitments that may limit our ability to commercialize OJEMDA or any other product. If we fail to comply with FDA-mandated requirements or if the

results of certain required post-marketing studies are negative, the FDA could withdraw approval, add warnings or narrow approved indications, which could affect the commercial success of our products.

In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials and the review process. For example, in May 2022, the Oncology Center of Excellence within the FDA advanced Project Optimus, an initiative to reform the dose optimization and dose selection paradigm in oncology drug development to emphasize selection of an optimal dose, which is a dose or doses that maximizes not only the efficacy of a drug but the safety and tolerability as well. This shift from the prior approach, which generally determined the maximum tolerated dose, may require sponsors to spend additional time and resources to further explore a product candidate's dose-response relationship to facilitate optimum dose selection in a target population. Other recent Oncology Center of Excellence initiatives have included Project FrontRunner, a new initiative with a goal of developing a framework for identifying candidate drugs for initial clinical development in the earlier advanced setting rather than for treatment of patients who have received numerous prior lines of therapies or have exhausted available treatment options.

Clinical trial failure may result from a multitude of factors, including flaws in trial design, dose selection, placebo effect, patient enrollment criteria, data integrity challenges or failure to demonstrate favorable safety or efficacy traits. Failure in clinical trials can occur at any stage. Companies in the pharmaceutical industry frequently suffer setbacks in the advancement of clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from clinical trials are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may further delay, limit or prevent marketing authorization. On the basis of our clinical trials, the FDA could delay, limit or deny approval of a product candidate for many reasons, including because the FDA may:

- not deem our product candidate to be safe and effective;
- determine that the product candidate does not have an acceptable benefit-risk profile;
- determine in the case of an NDA seeking accelerated approval that the NDA does not provide evidence that the product candidate represents a meaningful advantage over available therapies and, therefore, may deny approval;
- determine that ORR as the primary endpoint, complemented by key secondary endpoints, is insufficient to reliably define clinical benefit;
- not agree that the data collected from preclinical studies and clinical trials are acceptable or sufficient to support the submission of an NDA or other submission or to obtain marketing authorization, and may impose requirements for additional preclinical studies or clinical trials;
- determine that adverse events experienced by participants in our clinical trials represent an unacceptable level of risk;
- determine that the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- not accept clinical data from trials, which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States;
- disagree regarding the formulation, labeling and/or the specifications;
- not approve the manufacturing processes associated with our product candidate or may determine that a manufacturing facility does not have an acceptable compliance status;
- change approval policies or adopt new regulations; or
- not file a submission due to, among other reasons, the content or formatting of the submission.

We have not yet obtained FDA approval for our product candidates, pimasertib and DAY301. While the FDA approved the NDAs for the treatment of patients 6 months of age and older with relapsed or refractory pLGG harboring a BRAF fusion or rearrangement, or BRAF V600 mutation, there is no assurance that we will receive similar approval for OJEMDA from comparable regulatory authorities in foreign jurisdictions, which may limit our addressable market and could adversely affect our business, prospects, financial condition and results of operations.

If we seek to utilize any of the FDA's expedited programs, the FDA may not find our product candidates to be eligible for these programs and, if granted, these programs may not lead to faster development, regulatory review or approval of our product candidates.

The FDA has several expedited programs, including Fast Track, Priority Review, Breakthrough Therapy and Accelerated Approval, which are authorized by the Federal Food, Drug and Cosmetic Act, or FD&C Act, and implemented pursuant to FDA regulations and

guidance. None of these programs change the standard for FDA approval of a pharmaceutical product. We still must demonstrate substantial evidence of effectiveness and an acceptable safety profile to obtain marketing authorization.

We may seek to avail ourselves of one or more of the FDA's expedited programs. For example, we may seek Fast Track designation for one or more of our product candidates.

The FDA may grant a Fast Track designation to a drug that is intended for the treatment of a serious or life-threatening condition and nonclinical or clinical data demonstrates the potential to address unmet medical needs for this condition. The FDA has broad discretion whether to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. The FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program.

We have applied for and have been granted breakthrough therapy designation for tovorafenib in patients with advanced pLGG, and we may apply for breakthrough therapy designation for other product candidates or indications in the future. The FDA may designate a drug candidate as a potential breakthrough therapy if the drug candidate is intended, alone or in combination with one or more other drugs or drug candidates, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. For drug candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drug candidates designated as breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the NDA. The FDA may withdraw breakthrough therapy designations if it determines that the criteria for the designation is no longer met.

We may seek priority review of one or more of our other applications for marketing authorization, or we may receive priority review as part of other designations we may seek for one or more of our other product candidates. The FDA may grant priority review to an application if an application is for a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA may also grant priority review to supplements that propose a labeling change pursuant to a report on a pediatric study under Section 505A of the FD&C Act. Additionally, the FDA may grant priority review to any application or supplement for a drug submitted with a priority review voucher. We cannot assure you that the FDA would decide to grant priority review of any of our product candidates.

Even if we do receive Fast Track designation, breakthrough therapy designation or priority review for any of our product candidates, we may not experience expedited development, review or faster action on our applications for marketing authorization compared to products without such designations.

The accelerated approval pathway may be unavailable or, if available, may not lead to faster development, regulatory review or marketing authorization, and the use of the accelerated approval pathway does not necessarily increase the likelihood that our product candidates will receive marketing authorization.

Under the FDA's Accelerated Approval Program, and subject to the conditions set forth in Section 506(c) of the FD&C Act and FDA regulations, the FDA may approve a product for a serious or life-threatening disease or condition based on a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. The FDA generally reserves the use of accelerated approvals for situations in which the product candidate at issue provides a meaningful therapeutic benefit over existing treatments.

We may seek accelerated approval for one or more of our product candidates on the basis of a surrogate endpoint that we believe is reasonably likely to predict clinical benefit, such as ORR. The FDA may not agree with our conclusion that an endpoint we select is reasonably likely to predict clinical benefit, and thus the FDA may not agree that accelerated approval is appropriate based on that endpoint (even if the results on that endpoint are statistically significant), which could delay or preclude accelerated approval.

Products granted accelerated approval are subject to certain post-marketing requirements, which typically include a requirement to conduct one or more post-approval studies to confirm the clinical benefit of the product, which must be completed with due diligence. By the time of approval of the product, the FDA must set forth the conditions for the post-marketing studies which may include specific conditions and deadlines relating to the study protocol, enrollment targets, target completion date and other milestones. The FDA generally expects—and may require, as appropriate—the confirmatory study or studies to be underway at the time of the accelerated approval or within a specific time frame following approval. The FDA may disagree with our proposed clinical study designs for post-marketing confirmatory studies, and may require study conditions that are unfavorable to us, which could delay approval or lead to the withdrawal of a product approved under the accelerated approval pathway.

In addition, FDA regulations require that sponsors of products granted accelerated approval submit during the pre-approval review period copies of all promotional materials intended to be used within 120 days following marketing approval. After 120 days

following marketing approval, unless otherwise informed by the FDA, the sponsor must submit all promotional materials at least 30 days prior to use.

The accelerated approval pathway has come under scrutiny within the FDA, by Congress and by other stakeholders. The FDA has put increased focus on ensuring that confirmatory studies are conducted with diligence and, ultimately, that such studies confirm the benefit. For example, the FDA has convened its Oncologic Drugs Advisory Committee to review what the FDA has called "dangling" or "delinquent" accelerated approvals where confirmatory studies have not been completed or where results did not confirm benefit. In addition, in 2021, the Oncology Center of Excellence announced Project Confirm, which is an initiative to promote the transparency of outcomes related to accelerated approvals for oncology indications and provide a framework to foster discussion, research and innovation in approval and post-marketing processes, with the goal to enhance the balance of access and verification of benefit for therapies available to patients with cancer and hematologic malignancies.

Finally, Congress recently passed the Food and Drug Omnibus Reform Act of 2022, or FDORA, which implemented key reforms to the FDA's authorities with respect to accelerated approval, including strengthening requirements around post-approval studies, codifying procedures for withdrawal of a product approved under the expedited approval pathway and establishing an intra-agency Accelerated Approval Council to address accelerated approval policy. FDORA also added the failure to conduct post-approval studies with due diligence or to submit timely progress reports on such studies to the list of prohibited acts under the FD&C Act, which means that any such failures, whether they result from our actions or the actions of third parties, could provide the basis for enforcement actions to be brought against us, which may be costly to defend or we may be unsuccessful in our defense.

The FDA also has the authority to withdraw products approved under the accelerated approval pathway using expedited withdrawal procedures. Circumstances that may lead to such withdrawal include:

- the failure to conduct any required post-approval study of a product candidate with due diligence, including with respect to conditions specified by the FDA;
- a study required to verify and describe the predicted clinical benefit of a product candidate fails to verify and describe such benefit;
- other evidence demonstrates that the product candidate is not shown to be safe or effective under the conditions of use; or
- the sponsor's dissemination of false or misleading promotional materials relating to the relevant product candidate.

If any of our competitors were to receive full approval for an indication for which we are seeking accelerated approval before we receive accelerated approval, the indication we are seeking may no longer qualify as a condition for which there is an unmet medical need, and accelerated approval of our product candidate would be more difficult or may not occur at all.

We may not be able to obtain or maintain orphan drug designation or exclusivity for our product candidates.

We have obtained orphan drug designation in the United States and in the EU for use of tovorafenib in treating malignant glioma and glioma, respectively. We may seek orphan drug designation for tovorafenib in additional geographies or indications, or for pimasertib or DAY301 or any product candidates we may develop in the future. Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as "orphan drugs." Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or if the disease or condition affects more than 200,000 individuals in the United States and there is no reasonable expectation that the cost of developing and making available the drug for such disease or condition will be recovered from sales of the product in the United States.

Generally, if a product candidate with a U.S. orphan drug designation subsequently receives the first marketing authorization for the drug for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug for the same indication for a period of seven years. Orphan drug exclusivity in the United States may be lost if the FDA determines that the request for designation was materially defective or the drug in fact was ineligible for orphan-drug designation at the time the request for designation was submitted, or if the manufacturer is unable to assure a sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

The FDA may approve a subsequent application to market the same drug for the same indication during the exclusivity period in certain circumstances, such as if the subsequent product demonstrates clinical superiority (i.e., the subsequent product is safer, more effective or makes a major contribution to patient care) over the product with orphan exclusivity. Competitors, however, may receive approval of different products for the same indication for which the orphan product has exclusivity, or obtain approval for the same product but for a different indication than that for which the orphan product has exclusivity. Orphan drug designation also entitles a party to financial incentives, such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers.

In the EU, if a medicinal product is granted marketing authorization as an orphan medicinal product, it benefits from a period of orphan market exclusivity during which the European Medicines Agency, or the EMA, or a national regulator may not accept a marketing authorization application for a similar medicinal product in the same orphan indication. The applicable period of orphan

exclusivity is ten years in the EU, but this can be reduced to six years if a drug no longer meets the criteria for orphan drug designation. The EMA or a national regulator may accept an application and grant a marketing authorization for a similar medicinal product for the orphan indication during the exclusivity period if the similar product is safer, more effective or otherwise clinically superior to the orphan product.

We cannot assure you that any future application for orphan drug designation with respect to any other product candidate will be granted. If we are unable to obtain orphan drug designation with respect to other product candidates in the United States or other jurisdictions, we will not be eligible to obtain the period of market exclusivity that could result from orphan drug designation or be afforded the other incentives associated with orphan drug designation.

Moreover, a recent Eleventh Circuit decision in *Catalyst Pharmaceuticals, Inc. vs. FDA* regarding interpretation of the Orphan Drug Act exclusivity provisions as applied to drugs approved for orphan indications narrower than the drug's orphan designation has the potential to significantly broaden the scope of orphan drug exclusivity for such products. Specifically, the Eleventh Circuit held that orphan drug exclusivity precludes the FDA from approving another marketing application for the same drug for the same orphan-designated disease or condition for a period of seven years. Although the FDA has announced that it will not apply the Catalyst decision beyond the facts at issue in that case, Catalyst could serve as a precedent for future challenges to the FDA's orphan drug-related decisions, and, accordingly, could fundamentally change how companies rely on, or seek to work around, orphan drug exclusivity in the United States. Legislation has also been introduced that may reverse the Catalyst decision, but such legislation has not yet been passed.

We must comply with certain legal requirements and FDA policies, and may seek incentives under certain laws, relating to the development of drugs for pediatric patients, including the Pediatric Research Equity Act and the Best Pharmaceuticals for Children Act.

The Pediatric Research Equity Act, as amended, or PREA, requires that certain NDAs, Biologics License Applications, or BLAs, and NDA/BLA supplements contain assessment reports regarding the safety and efficacy of the product for the claimed indications in all relevant pediatric subpopulations to support dosing and administration for each pediatric subpopulation for which the product has been assessed to be safe and effective. In addition, PREA requires a molecularly targeted pediatric cancer investigation for an original NDA or BLA for a new active ingredient if the product candidate is intended to treat an adult cancer and is directed at a molecular target that the FDA determines to be substantially relevant to the growth or progression of a pediatric cancer, which may be different than the claimed adult cancer indication. PREA requires these pediatric studies be conducted using appropriate formulations for each age group that is studied, and an applicant must seek approval of any pediatric formulations that are used. The FDA may grant deferrals of PREA requirements or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to a drug for an indication for which orphan designation has been granted, except that PREA will apply to an original NDA or BLA that is subject to the molecularly targeted pediatric cancer investigation requirement. Even if we are deemed exempt from PREA requirements for one application, any of our other applications may be subject to PREA requirements.

Under the Best Pharmaceuticals for Children Act, or the BPCA, the FDA can grant pediatric exclusivity to a sponsor that conducts pediatric studies requested by the FDA in a document called a Written Request. We may seek pediatric exclusivity for one or more of our product candidates under the BPCA, although we may not be granted such exclusivity. Pediatric exclusivity, if granted, adds six months to the end of certain unexpired statutory exclusivity periods and may also extend unexpired patent terms, depending on whether the application is an NDA or BLA. Whether this six-month extension is granted depends on the voluntary completion of pediatric studies in accordance with and in response to a Written Request for such studies, the submission of the study reports to the FDA within the timeframe required by the BPCA and the FDA's acceptance of the study reports. The FDA has indicated a strong preference to issue Written Requests only for studies that are in addition to and/or different from pediatric studies required under PREA (if applicable).

In general, pediatric drug development is an area that recently has been, and may continue to be, subject to evolving statutory requirements and regulatory standards, so some uncertainty exists with respect to expectations for pediatric drug development generally.

We may seek a rare pediatric disease designation for one or more of our product candidates under the FDA's Rare Pediatric Disease Priority Review Voucher Program. Even if we were to obtain marketing authorization for a product with a rare pediatric disease designation, the Rare Pediatric Disease Priority Review Voucher Program may no longer be in effect at the time of such approval or we might not be able to capture the value of the Rare Pediatric Disease Priority Review Voucher Program.

OJEMDA was granted rare pediatric designation by the FDA in May 2021 for the treatment of LGGs harboring an activating RAF alteration that disproportionately affects children. We submitted the OJEMDA NDAs as a rare pediatric designation marketing application, and the FDA conditionally designated the marketing application as a "rare pediatric disease product application" pending the final determination at the time of approval or licensure on whether the application meets all of the eligibility criteria set forth in section 529(a)(4) of the FD&C Act. On April 23, 2024, the FDA approved the NDAs for the treatment of patients 6 months of age and

older with relapsed or refractory pLGG harboring a BRAF fusion or rearrangement, or BRAF V600 mutation, and in connection with the accelerated approval, Day One received a Priority Review Rare Pediatric Disease Voucher, or PRV.

Congress authorized the FDA to award priority review vouchers to sponsors of certain rare pediatric disease product applications that meet the specified criteria. These vouchers are designed to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases.

Specifically, under this program, a sponsor who receives an approval for a drug or biologic for a "rare pediatric disease" may qualify for a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product. The sponsor of a rare pediatric disease drug product receiving a priority review voucher may transfer (including by sale) the voucher to another sponsor. On May 29, 2024, we entered into an asset purchase agreement, pursuant to which we agreed to sell our rare pediatric disease PRV to an undisclosed buyer for gross proceeds of $108.0 million. Following the sale, we are no longer eligible to take advantage of the incentives under the rare pediatric disease PRV, including priority review of a subsequent marketing application. The voucher may be further transferred any number of times before the voucher is used, as long as the sponsor making the transfer has not yet submitted the application. Although the voucher can be sold or transferred to third parties, there is no guarantee that we will be able to receive such voucher in the future for any of our current or future product candidates or that we will realize any value if we receive and were to sell any such voucher.

For the purposes of this program, a rare pediatric disease is a (i) serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents; and (ii) rare disease or condition within the meaning of the Orphan Drug Act. The FDA may determine that an application for one or more of our product candidates does not meet the eligibility criteria for a priority review voucher upon approval.

Moreover, under the current statutory sunset provisions, the FDA generally may not award rare pediatric disease priority review vouchers after September 30, 2024. However, if the sponsor has received rare pediatric disease designation for a drug no later than September 30, 2024, the FDA may award a rare pediatric disease priority review voucher if the drug is approved by September 30, 2026.

If we or a business partner are unable to successfully develop, validate, obtain marketing authorization for and commercialize any companion diagnostic tests that are deemed necessary for the use of any of our product candidates, or experience significant delays in doing so, we may not be able to obtain marketing authorization for, or realize the full commercial potential of, one or more of our product candidates.

Diagnostic tests can be useful in identifying patients who are most likely to benefit from a particular therapeutic drug product, among other potential uses. If a regulatory authority determines that an in vitro diagnostic test is necessary for the safe and effective use of a corresponding therapeutic product, that test is referred to as a "companion diagnostic." Diagnostics that are not essential for the safe and effective use of a therapeutic product but that may aid in the benefit-risk decision-making about the use of the therapeutic product (such as to identify a subset of the indicated patient population for the therapeutic product that may respond particularly well) are typically referred to as "complementary diagnostics." In the future, we may evaluate opportunities to develop, either by ourselves or with collaborators, companion or complementary diagnostic tests for our product candidates for certain indications.

If a companion diagnostic is needed for a therapeutic product, the companion diagnostic is generally developed in conjunction with the clinical program for an associated therapeutic product. To date, the FDA has required premarket approval of the vast majority of companion diagnostics for cancer therapies. Generally, when a companion diagnostic is essential to the safe and effective use of a drug product, the FDA generally requires that the companion diagnostic be approved before or concurrent with approval of the therapeutic product and before such product can be commercialized (except in limited circumstances). Where a companion diagnostic must be used to identify patients who are likely to benefit from the therapeutic product, the therapeutic product's labeling typically limits the use of the therapeutic product to only those patients who express the specific genetic alteration or other biomarker that the companion diagnostic was developed to detect. By contrast, complementary diagnostics are not typically referenced in the indications for the therapeutic product (i.e., the therapeutic product is not limited to use in biomarker positive patients) but the complementary diagnostic may be described in other areas of the therapeutic product labeling, such as when describing clinical study results for biomarker positive and negative patient subpopulations. While a complementary diagnostic is also typically developed in conjunction with the clinical program for an associated therapeutic product, the FDA may not require that the complementary diagnostic be approved before or concurrent with approval of the therapeutic product.

Development of a companion or complementary diagnostic could include additional meetings with regulatory authorities, such as a pre-submission meeting and the requirement to comply with the FDA's investigational device exemption regulations for clinical studies involving the diagnostic. In the case of an investigational diagnostic that is designated as "significant risk device," approval of an investigational device exemption application by an IRB and the FDA is required before such diagnostic may be used in conjunction with the clinical trials for a corresponding product candidate.

To be successful in developing, validating, obtaining approval of and commercializing a companion or complementary diagnostic, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. We have no prior experience with medical device or diagnostic test development. If we choose to develop and seek FDA approval for companion diagnostic tests on our own, we will require additional personnel. We may rely on third parties for the design, development, testing, validation and manufacture of companion diagnostic tests for our therapeutic product candidates that require companion diagnostic tests or would benefit from complementary diagnostics, the application for and receipt of any required marketing authorizations and the commercial supply of these diagnostics. If these parties are unable to successfully develop companion diagnostics for these therapeutic product candidates, or experience delays in doing so, we may be unable to enroll enough patients for our current and planned clinical trials, the development of these therapeutic product candidates may be adversely affected, these therapeutic product candidates may not obtain marketing authorization and we may not realize the full commercial potential of any of these therapeutics that obtain marketing authorization. For any product candidate for which a companion diagnostic is necessary to select patients who may benefit from use of the product candidate, any failure to successfully develop a companion diagnostic may cause or contribute to delayed enrollment of our clinical trials, and may prevent us from initiating a pivotal trial. In addition, the commercial success of any of our product candidates that require a companion diagnostic will be tied to and dependent upon the receipt of required marketing authorizations and the continued ability of such third parties to make the companion diagnostic commercially available to us on reasonable terms in the relevant geographies. There is no guarantee that physicians will adopt any particular companion diagnostic, be willing to understand how to use it, how to obtain reimbursement for it or how to explain it to patients or dedicate staff to using it. Any failure to do so could materially harm our business, results of operations and financial condition.

For each product and product candidate for which marketing authorization is granted, including OJEMDA, the terms of approvals, ongoing regulation of our products or other post-approval restrictions may limit how we manufacture and market our products and compliance with such requirements may involve substantial resources, which could materially impair our ability to generate revenue in line with our expectations.

For each product and product candidate for which marketing authorization is granted, including OJEMDA, an approved product and the marketing authorization holder are subject to ongoing regulation by the FDA and other regulators. Regulators may impose post-marketing requirements and elicit post-marketing commitments, which may be onerous and subject us to ongoing review and extensive regulation. For example, the FDA may request or require post-marketing clinical studies, enhanced pharmacovigilance programs, additional reporting requirements and other obligations at the time of approval or after approval. The FDA also may impose a REMS under Section 505-1 of the FD&C Act in order to ensure that the benefits of our product candidates outweigh their risks. Additionally, either at the time or approval or after approval, the FDA could invoke its authority under Section 505(o) of the FD&C Act and require costly post-marketing safety studies, including clinical trials, and/or epidemiologic surveillance to monitor the safety of our approved products in order to assess a known risk related to the product, assess signals of serious risks related to the product or identify an unexpected serious risk when available data indicates the potential for a serious risk.

In addition, any product candidates for which we receive accelerated approval from the FDA are required to undergo one or more clinical trials to confirm the clinical benefit of the product. If confirmatory studies fail to meet their efficacy endpoints, the FDA may withdraw approval of the product pursuant to expedited withdrawal authorities. There is no assurance that any such product will successfully advance through its confirmatory clinical trial(s). Therefore, even if a product candidate receives accelerated approval from the FDA, such approval may be withdrawn at a later date.

We must also comply with requirements concerning advertising and promotion for any of our product candidates for which we obtain marketing authorization. Further, there are additional requirements regarding promotional communications if our products are approved through the accelerated approval pathway. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we will not be able to promote any products we develop for indications or uses for which they are not approved.

In addition, manufacturers of approved products and those manufacturers' facilities are required to ensure that quality control and manufacturing procedures conform to current good manufacturing practices, or cGMPs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We and our CMOs could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs, including pre-approval inspections of any manufacturing facilities proposed to commercially manufacture our product candidates, the success of which would be required prior to a commercial product launch. Accordingly, assuming we obtain marketing authorization for one or more of our product candidates, we and our CMOs will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control.

If we are not able to comply with all of our post-approval regulatory requirements, we could have the marketing authorizations for our products withdrawn by regulatory authorities and our ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. In addition, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

Any product for which we obtain marketing authorization, including OJEMDA, will be subject to ongoing enforcement of post-marketing requirements by regulatory agencies, and we could be subject to substantial penalties, including withdrawal of our product from the market, if we fail to comply with all regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

Any product for which we obtain marketing authorization, such as OJEMDA, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include, but are not limited to, restrictions governing promotion of an approved product, submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents and requirements regarding drug distribution and the distribution of samples to physicians and recordkeeping.

The FDA and other federal and state agencies, including the Department of Justice, closely regulate compliance with all requirements governing prescription drug products, including requirements pertaining to marketing and promotion of drugs in accordance with the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements. For example, the FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Violations of such requirements may lead to investigations alleging violations of the FD&C Act and other statutes, including the False Claims Act and other federal and state healthcare fraud and abuse laws as well as state consumer protection laws. Our failure to comply with all regulatory requirements, and later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, may yield various results, including:

- litigation involving patients taking our products;
- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- voluntary or mandatory recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing authorizations;
- damage to relationships with any potential collaborators;
- unfavorable media coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance by us or any future collaborator with regulatory requirements, including safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population can also result in significant financial penalties. Further, if any of these actions were to occur, we may have to discontinue the commercialization of our product, OJEMDA, and product candidates, limit our sales and marketing efforts, conduct further post-approval studies and/or discontinue or change any other ongoing clinical studies, which in turn could result in significant expense and delay and/or limit our ability to generate sales revenues.

Our failure to obtain marketing authorization in foreign jurisdictions would prevent OJEMDA and our product candidates from being marketed in those jurisdictions, and any approval we are granted for our product candidates in the United States would not assure approval of product candidates in foreign jurisdictions.

In order to market and sell our products in any jurisdiction outside the United States, we must obtain separate marketing authorizations and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. Further, FDA approval of OJEMDA does not guarantee approval in jurisdictions outside of the United States. The marketing authorization

process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to submit for marketing authorizations and may not receive necessary approvals to commercialize our products in any market.

Our current and future relationships with customers and third-party payors may be subject to applicable anti-kickback, fraud and abuse, transparency, health privacy and other healthcare laws and regulations, which could expose us to significant penalties, including criminal, civil and administrative penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, including physicians, and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing authorization. Our current and future arrangements with healthcare providers, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, as well as market, sell and distribute, any products for which we obtain marketing authorization. Restrictions under applicable federal and state healthcare laws and regulations that may be applicable to our business include the following:

• the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

• the federal civil false claims laws, including the False Claims Act, which can be enforced by civil whistleblower or qui tam actions on behalf of the government, and criminal false claims laws and the civil monetary penalties law, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment by a federal government program, or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government;

• the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, regardless of the payor (e.g. public or private), and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

• HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, imposes requirements on certain covered healthcare providers, health plans and healthcare clearinghouses, as well as their respective business associates and their subcontractors that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of such individually identifiable health information;

• the federal transparency requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively referred to as the ACA, require certain manufacturers of drugs, devices, biologics and medical supplies to annually report to the Centers for Medicare & Medicaid Services, or CMS, information related to payments and other transfers of value provided to teaching hospitals, as well as ownership and investment interests held by physicians, defined to include doctors, dentists, optometrists, podiatrists and chiropractors, as well as ownership and investment interests held by physicians and their immediate family members. Since January 1, 2021, manufacturers are required to collect information regarding payments and transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified nurse anesthetists and certified nurse-midwives for reporting in the following year. The reported information is made available on a public website; and

• analogous state laws and regulations such as state anti-kickback and false claims laws and analogous non-U.S. fraud and abuse laws and regulations, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by state payors and non-governmental third-party payors, including private insurers. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance regulations promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing, including price increases. Certain state and local laws require the registration of pharmaceutical sales representatives. Certain state and non-U.S. laws, many of which differ from each other in significant ways and often are not preempted by HIPAA, also govern the privacy and security of health information in some circumstances, thus complicating compliance efforts.

Efforts to ensure that our internal business processes and business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional integrity reporting and oversight obligations and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil and administrative sanctions, including exclusions from government funded healthcare programs, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

Existing, recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing authorization of and commercialize our product candidates and decrease the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing authorization of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any products for which we obtain marketing authorization.

For example, in March 2010, the ACA was signed into law. The ACA is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the ACA of importance to our potential product candidates are the following:

• annual fees and taxes on manufacturers of certain branded prescription drugs;

• an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic products;

• a Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;

• a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;

• an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations;

• expansion of healthcare fraud and abuse laws, including the False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;

• extension of manufacturers' Medicaid rebate liability;

• expansion of eligibility criteria for Medicaid programs;

• expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;

• requirements to report financial arrangements with physicians, as defined by such law, and teaching hospitals;

• a requirement to annually report drug samples that manufacturers and distributors provide to physicians; and

• a Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research.

There have been executive, judicial and Congressional challenges to repeal or replace certain aspects of the ACA, including measures taken during the Trump administration. The Trump administration released executive orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties, since January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance, eliminating the implementation of certain ACA-mandated fees and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. In November 2020, the U.S. Supreme Court held oral arguments on

the U.S. Court of Appeals for the Fifth Circuit's decision that held that the individual mandate is unconstitutional. On February 10, 2021, the Biden administration withdrew the federal government's support for overturning the ACA. In June 2021, the U.S. Supreme Court remanded the case with instructions to dismiss for lack of standing. However, the U.S. Supreme Court did not decide the ultimate issue of the validity of the individual mandate. Thus, there may be other efforts to challenge the individual mandate or to challenge, repeal or replace the ACA. It is unclear how the U.S. Supreme Court ruling, other such litigation and the healthcare reform measures of the current presidential administration will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals for spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction, triggering the legislation's automatic reduction to several government programs. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which began in 2013, and due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through December 31, 2021 due to the COVID-19 pandemic, unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding.

Further, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drug products. At the federal level, the last presidential administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. The current presidential administration is also focused on drug pricing. For example, on September 9, 2021, the Biden administration published a wide-ranging list of policy proposals to lower prescription drug prices, including by allowing Medicare to negotiate prices and disincentivizing price increases, and to support market changes that strengthen supply chains, promote biosimilars and generic drugs and increase price transparency. These initiatives recently culminated in the enactment of the Inflation Reduction Act, or IRA, in August 2022, which will, among other things, allow the U.S. Department of Health and Human Services, or HHS, to negotiate the price of certain drugs and biologics that CMS reimburses under Medicare Part B and Part D. The IRA's negotiation program will apply to high-expenditure single-source drugs that have been approved for at least 7 years (11 years for biologics), among other negotiation selection criteria. One statutory exemption from the negotiation program is for a drug that has only a single orphan drug designation and is approved only for an indication or indications within the scope of such designation. The negotiated prices, which for the first round of selected drugs announced August 29, 2023 will become effective in 2026, will be capped at a statutorily-determined ceiling price. The IRA also penalizes drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. In addition, the law eliminates the "donut hole" under Medicare Part D beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and requiring manufacturers to subsidize, through a newly established manufacturer discount program, 10% of Part D enrollees' prescription costs for brand drugs below the out-of-pocket maximum, and 20% once the out-of-pocket maximum has been reached. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. These IRA provisions will take effect progressively starting in 2023, although the drug negotiation provisions of the IRA are currently the subject of legal challenges. In addition, the Secretary of the HHS recently proposed testing three new models for pricing efficiency, including one that develops payment methods for drugs approved under accelerated approval, in consultation with the FDA, to encourage timely confirmatory trial completion and improve access to post-market safety and efficacy data with the goal of reducing Medicare spending on drugs that have no confirmed clinical benefit. Further, at the state level, individual states have increasingly introduced and passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including: restricting price, reimbursement, discounts, product access and marketing; imposing drug price and cost disclosure and transparency requirements; permitting importation from other countries; and encouraging bulk purchasing.

We expect that additional state and federal healthcare reform measures, including potentially significant additional changes to current drug pricing and reimbursement structures, will be adopted in the future, particularly if there is a change in presidential administration. Current and future reform measures may result in more rigorous coverage criteria and in additional downward pressure on the prices that we receive for any approved product. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate future revenue in line with our expectations, attain profitability or commercialize OJEMDA and our product candidates.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing authorizations of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may

significantly delay or prevent marketing authorization, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Further, in June 2024, the U.S. Supreme Court reversed its longstanding approach under the Chevron doctrine, which provided for judicial deference to regulatory agencies, including the FDA. As a result of this decision, we cannot be sure whether there will be increased challenges to existing agency regulations or how lower courts will apply the decision in the context of other regulatory schemes without more specific guidance from the U.S. Supreme Court. For example, this decision may result in more companies bringing lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, which could undermine the FDA's authority, lead to uncertainties in the industry, and disrupt the FDA's normal operations, which could impact the timely review of any regulatory filings or applications we submit to the FDA.

Governments outside of the United States tend to impose strict price controls, which may adversely affect our future revenues.

In some countries, including Canada and certain member states of the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing authorization for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidates to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states, and parallel trade, such as arbitrage between low-priced and high-priced member states, can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any products, if approved in those countries. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication or other countries.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain product candidates and products outside of the United States and require us to develop and implement costly compliance programs.

If we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business and their party agents from paying, offering, authorizing payment or offering anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of such third party in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the company, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. We are also subject to U.S. laws and regulations governing export controls, as well as economic sanctions and embargoes on certain countries and persons. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing or selling certain product candidates and products outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The U.S. Securities and Exchange Commission, or the SEC, also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We and our third-party contractors are subject to numerous foreign, federal, state and local environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or

injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources, including any available insurance. We could also be held liable for unexpected safety events that could happen in our business offices.

In addition, our leasing and operation of real property may subject us to liability pursuant to certain of these laws or regulations. Under existing U.S. environmental laws and regulations, current or previous owners or operators of real property and entities that disposed or arranged for the disposal of hazardous substances may be held strictly, jointly and severally liable for the cost of investigating or remediating contamination caused by hazardous substance releases, even if they did not know of and were not responsible for the releases.

We could incur significant costs and liabilities which may adversely affect our financial condition and operating results for failure to comply with such laws and regulations, including, among other things, civil or criminal fines and penalties, property damage and personal injury claims, costs associated with upgrades to our facilities or changes to our operating procedures or injunctions limiting or altering our operations.

Although we maintain liability insurance to cover us for costs and expenses we may incur due to injuries to our employees, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations, which are becoming increasingly more stringent, may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations. We can face serious consequences for violations.

U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations prohibit, among other things, companies and their employees, agents, CROs, CMOs, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of these laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We also expect our non-U.S. activities to increase over time. We expect to rely on third parties for research, preclinical studies and clinical trials and/or to obtain necessary permits, licenses, patent registrations and other marketing authorizations. We can be held liable for the corrupt or other illegal activities of our personnel, agents or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

We are developing our current product candidates, and may continue to develop future product candidates, in combination with other therapies, which would expose us to additional risks.

We are developing our current product candidates in combination with one or more currently approved cancer therapies or therapies in development. Even if our current or future product candidates, including pimasertib and DAY301, receive marketing authorization or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or comparable foreign regulatory authorities could revoke approval of the therapy used in combination with any of our product candidates, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our product candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the need to identify other combination therapies for our product candidates or our own products being removed from the market or being less successful commercially.

We may also evaluate our current product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA or comparable foreign regulatory authorities. We will not be able to market and sell any product candidate in combination with any such unapproved cancer therapies that do not ultimately obtain marketing authorization.

If the FDA or comparable foreign regulatory authorities do not approve or withdraw their approval of these other therapies, or if safety, efficacy, commercial adoption, manufacturing or supply issues arise with the therapies we choose to evaluate in combination with any of our current or future product candidates, we may be unable to obtain approval of or successfully market any one or all of

the current or future product candidates we develop. Additionally, if the third-party providers of therapies or therapies in development used in combination with our current or future product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our current or future product candidates, or if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

We have limited experience as a commercial company and the sales, marketing, and distribution of OJEMDA or any future approved products may be unsuccessful or less successful than anticipated.

We recently began commercializing our first product, OJEMDA, in the United States. As a company, we had no prior experience commercializing a product. The success of our commercialization efforts for OJEMDA and any future approved products is difficult to predict and subject to the effective execution of our business plan, including, among other things, the continued development of our internal sales, marketing, and distribution capabilities and our ability to navigate the significant expenses and risks involved with the development and management of such capabilities.

For example, we have completed hiring in areas to support commercialization, including in sales management, sales representatives, marketing, access and reimbursement, sales support, and distribution. There are significant expenses and risks involved with establishing our own sales, marketing, and distribution capabilities, including our ability to hire, retain, and appropriately incentivize qualified individuals, provide adequate training to sales and marketing personnel, and effectively manage geographically dispersed sales and marketing teams to generate sufficient demand. Any failure or delay in the development of these capabilities could delay or negatively affect the success of our commercialization efforts and our business. For example, the commercialization of OJEMDA may not develop as planned or anticipated, which may require us to, among others, adjust or amend our business plan and incur significant expenses.

Alternatively, we may license certain rights with respect to our products or product candidates to collaborators and rely on the assistance and guidance of those collaborators. We may also seek collaborations to secure marketing authorizations and commercialize our products outside of the United States. We cannot assure that any collaboration(s) will result in short-term or long-term benefit to the company. If we choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems, we will be required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration and such arrangements may prove to be less profitable than commercializing the product on our own. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our products and product candidates, we may not generate substantial revenues, if any, from them or be able to reach or sustain profitability.

Given our lack of experience commercializing products, we do not have a track record of successfully executing on the commercialization of an approved product. If we are unsuccessful in accomplishing our objectives and executing on our business plan, or if the commercialization of OJEMDA or any future approved products does not develop as planned, we may require significant additional capital and financial resources, we may not become profitable, and we may not be able to compete against more established companies in our industry.

Risks Related to Our Reliance on Third Parties

We rely, and intend to continue to rely, on third parties to conduct our clinical trials and perform some of our research and potential preclinical studies. If these third parties do not satisfactorily carry out their contractual duties, fail to comply with applicable regulatory requirements or do not meet expected deadlines, our development programs may be delayed or subject to increased costs or we may be unable to obtain marketing authorization, each of which may have an adverse effect on our business, financial condition, results of operations and prospects.

We do not have the ability to independently conduct all aspects of our clinical trials ourselves. As a result, we are dependent on third parties to conduct our ongoing and planned clinical trials of tovorafenib, pimasertib and DAY301, and any preclinical studies and clinical trials of any future products and product candidates. The timing of the initiation and completion of these trials will therefore be partially controlled by such third parties and may result in delays to our development programs. Since such third parties partially control the progress of these trials, they may also publish the data related to these trials prior to obtaining or without our approval for doing so. Specifically, we expect CROs, independent clinical investigators and consultants to play a significant role in the conduct of these trials and the subsequent collection and analysis of data. For example, in addition to the Phase 1 clinical trial run by Dana Farber Cancer Institute in collaboration with PNOC, the Children's Oncology Group, a National Cancer Institute-supported clinical trials group and the world's largest organization devoted exclusively to childhood and adolescent cancer research, is developing a group-wide clinical trial of tovorafenib in relapsed Langerhans cell histiocytosis. However, these investigators, CROs and other third parties are not our employees, and we will not be able to control all aspects of their activities. Nevertheless, we are responsible for ensuring that each clinical trial is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the investigators, CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are

required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA for products and product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical trial investigators and clinical trial sites. If we or any of our CROs or clinical trial sites fail to comply with applicable GCP requirements, the data generated in our clinical trials may be deemed unreliable, and the FDA may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that our clinical trials comply with GCPs. In addition, our clinical trials must be conducted with products and product candidates produced under cGMP regulations. Our failure or the failure of third parties on whom we rely to comply with these regulations may require us to stop and/or repeat clinical trials, which would delay the marketing authorization process.

There is no guarantee that any such CROs, clinical trial investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. In addition, these third parties may be subject to supply chain or inflationary pressures that limit their ability to achieve anticipated timelines or result a greater cost to us. For example, we are aware of a shortage of non-human primates available for preclinical studies and although that is not expected to impact our current business if we begin new product development programs we could be subject to longer development times or difficulty completing necessary research. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, otherwise perform in a substandard manner or terminate their engagements with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. If our clinical trial site terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in such clinical trial unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible.

In addition, with respect to investigator-sponsored trials that may be conducted, we would not control the design or conduct of these trials, and it is possible that the FDA will not view these investigator-sponsored trials as providing adequate support for future clinical trials or market approval, whether controlled by us or third parties, for any one or more reasons, including elements of the design or execution of the trials or safety concerns or other trial results. We expect that such arrangements will provide us certain information rights with respect to the investigator-sponsored trials, including access to and the ability to use and reference the data, including for our own regulatory submissions, resulting from the investigator-sponsored trials. However, we would not have control over the timing and reporting of the data from investigator-sponsored trials, nor would we own the data from the investigator-sponsored trials. If we are unable to confirm or replicate the results from the investigator-sponsored trials or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development. Further, if investigators or institutions breach their obligations with respect to the clinical development of OJEMDA or our product candidates, or if the data proves to be inadequate compared to the firsthand knowledge we might have gained had the investigator-sponsored trials been sponsored and conducted by us, then our ability to design and conduct any future clinical trials ourselves may be adversely affected. The investigators may design clinical trials with clinical endpoints that are more difficult to achieve, or in other ways that increase the risk of negative clinical trial results compared to clinical trials that we may design on our own. Negative results in investigator-sponsored clinical trials could have a material adverse effect on our efforts to obtain marketing authorization for our product candidates and the public perception of our product candidates. Additionally, the FDA may disagree with the sufficiency of our right of reference to the preclinical, manufacturing or clinical data generated by these investigator-sponsored trials, or our interpretation of preclinical, manufacturing or clinical data from these investigator-sponsored trials. If so, the FDA may require us to obtain and submit additional preclinical, manufacturing or clinical data.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors for whom they may also be conducting clinical trials or other pharmaceutical product development activities that could harm our competitive position. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing authorizations for OJEMDA, pimasertib, DAY301 or any future product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our products.

The manufacture of pharmaceutical products, including OJEMDA and our product candidates including pimasertib and DAY301, is complex. Our third-party manufacturers may encounter difficulties in production, which could delay or entirely halt their ability to supply our product candidates for clinical trials or, if approved, for commercial sale.

We do not have any manufacturing facilities, and we currently contract with certain third-party manufacturers in China. We rely, and expect to continue to rely, on third parties for the manufacture of OJEMDA and our product candidates for clinical testing, product development purposes, to support regulatory application submissions, as well as for commercial manufacture of our product candidates. In addition, we expect to contract with analytical laboratories for release and stability testing of OJEMDA and our product candidates. This reliance on third parties increases the risk that we will not have sufficient quantities of OJEMDA or our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts and cause the FDA to withdraw certain designations, including orphan drug designation. For example, we cannot be sure to what extent the supply chain issues caused by geopolitical uncertainty and public health epidemics, may impact our ability to procure sufficient supplies for the development of OJEMDA and our product candidates and what, if any, impact that may have on our facilities and operations in the region, including but not limited to a decrease or disruption of production, increased costs

of production or other interruptions in our supply chain. In addition, any disruption in production or inability of our manufacturers, specifically in China, to produce adequate quantities to meet our needs, whether as a result of a natural disaster or other causes, could impair our ability to operate our business on a day-to-day basis and to continue our development of OJEMDA and our product candidates. Furthermore, since these manufacturers are located in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the United States or Chinese governments, political unrest or unstable economic conditions in China. Legislation has been introduced in Congress to limit certain U.S. biotechnology companies from using equipment or services produced or provided by select Chinese biotechnology companies, including those affiliated with the manufacture of our API, Wuxi STA, and others in Congress have advocated for the use of existing executive branch authorities to limit those Chinese service providers' ability to engage in business in the U.S. We cannot predict what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation.

Any of these matters could materially adversely affect our business, financial condition and results of operations. In addition, disruptions in logistics routes and transportation capabilities could disrupt our supply chain. And, if we experience unexpected spikes in demand over time, we risk running out of our necessary supplies.

We entered into a manufacturing and supply agreement with Quotient for drug manufacturing of OJEMDA and a packaging agreement with Sharp Corporation, or Sharp, for the packaging and serialization of OJEMDA. Supply chain issues, such as those related to certain packaging material, may negatively impact our ability to package and deliver OJEMDA and our product candidates if not managed effectively. Moreover, if any of our existing or future contract manufacturers or suppliers fail to perform satisfactorily, it could delay development or regulatory approval of our drug candidates or commercialization of our drugs, which could negatively impact our results of operations and business.

We may be unable to enter into additional agreements with third-party manufacturers or suppliers or do so on favorable terms. Our anticipated reliance on a limited number of third party-manufacturers or suppliers exposes us to the following risks:

- reliance on the third party for regulatory, compliance and quality assurance;
- reliance on the third party for product development, analytical testing and data generation to support regulatory applications;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier, the issuance of an FDA Form 483 notice or warning letter or other enforcement action by the FDA or other regulatory authority;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us;
- carrier disruptions or increased costs that are beyond our control; and
- failure to deliver our drugs under specified storage conditions and in a timely manner.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If the FDA determines that our CMOs are not in compliance with FDA laws and regulations, including those governing cGMPs, the FDA may not approve an NDA until the deficiencies are corrected or we replace the manufacturer in our application with a manufacturer that is in compliance. Moreover, our failure, or the failure of our third-party manufacturers and suppliers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. In addition, approved products and the facilities at which they are manufactured are required to maintain ongoing compliance with extensive FDA requirements and the requirements of other similar agencies, including ensuring that quality control and manufacturing procedures conform to cGMP requirements. As such, our CMOs are subject to continual review and periodic inspections to assess compliance with cGMPs. Furthermore, although we do not have day-to-day control over the operations of our CMOs, we are responsible for ensuring compliance with applicable laws and regulations, including cGMPs.

In addition, our third-party manufacturers and suppliers are subject to numerous environmental, health and safety laws and regulations, including those governing the handling, use, storage, treatment and disposal of waste products, and failure to comply with such laws and regulations could result in significant costs associated with civil or criminal fines and penalties for such third parties. Based on the severity of regulatory actions that may be brought against these third parties in the future, our clinical or commercial supply of drug and packaging and other services could be interrupted or limited, which could harm our business.

OJEMDA and our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. As a result, we may not obtain access to these facilities on a priority basis or at all. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

As we prepare for later-stage clinical trials and commercialization of OJEMDA, we will need to take steps to increase the scale of production of OJEMDA and our product candidates. Other than for our product OJEMDA, we have not yet scaled up the manufacturing process for any of our product candidates and may need to scale further to support future supply needs for any of our product candidates. Third-party manufacturers may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up or commercial activities. For example, if microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing authorization. If our current CMOs for clinical testing cannot perform as agreed, we may be required to replace such CMOs. Although we believe that there are several potential alternative manufacturers who could manufacture OJEMDA or our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement manufacturer or be able to reach agreement with any alternative manufacturer. Further, our third-party manufacturers may experience manufacturing or shipping difficulties due to resource constraints or as a result of natural disasters, labor disputes, unstable political environments or public health epidemics. If our current third-party manufacturers cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or at all.

Our current and anticipated future dependence upon others for the manufacture of OJEMDA or our product candidates may adversely affect our future profit margins and our ability to commercialize any products that obtain marketing authorization on a timely and competitive basis.

We rely on a limited number of suppliers for raw materials and any disruptions arising from our sole suppliers could result in delays in our clinical trials or otherwise adversely affect our business and results of operations.

We rely on a limited number of suppliers, some of whom are our sole source for certain materials, and some of whom are based in foreign jurisdictions. Our small number of suppliers involves a number of additional risks, including risks related to supplier capacity constraints, component availability, price increases, timely delivery, component quality, failure of a key supplier to remain in business and adjust to market conditions, including inflation and changes in interest rates, actual or perceived instability in the global banking system, uncertainty with respect to the federal debt ceiling and budget and potential government shutdowns related thereto, natural disasters, fire, regional geopolitical conflicts, acts of terrorism, pandemics, or other catastrophic events. Further, in the case of materials for which we have a sole supplier, even if we are able to replace any raw materials or other materials with an alternative, such alternatives may cost more, result in lower yields or not be as suitable for our purposes. In addition, some of the materials that we use to manufacture OJEMDA and our product candidates are complex materials, which may be more difficult to substitute. Therefore, any disruptions arising from our sole suppliers could result in delays and additional regulatory submissions, which may adversely affect our business and results of operations.

We may enter into collaborations with third parties for the development and commercialization of OJEMDA and our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of OJEMDA and our product candidates.

We may seek third-party collaborators for the development and commercialization of OJEMDA and some of our product candidates on a select basis. We have not entered into any collaborations to date. Our likely collaborators for any future collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for a future collaboration will depend, among other things, upon our assessment of the future collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors.

If we do enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our future collaborators dedicate to the development or commercialization of OJEMDA and our product candidates. Our ability to generate revenues from these arrangements will depend on our future collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations with future collaborators involving OJEMDA and our product candidates would pose numerous risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected;

- collaborators may de-emphasize or not pursue development and commercialization of OJEMDA and our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus, including as a result of a sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;

• collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon OJEMDA or a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

• collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with OJEMDA or our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

• a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product relative to other products;

• collaborators may reassign manufacturing responsibilities to themselves or a new CMO, which would require that any new manufacturing facility also comply with cGMPs. The FDA or another regulator could decide to conduct an inspection of any new manufacturing facility and a material noncompliance could delay the launch of commercial manufacturing at such facility;

• collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;

• disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of OJEMDA or our product candidates or that result in costly litigation or arbitration that diverts management attention and resources;

• collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable products or product candidates;

• collaboration agreements may not lead to development or commercialization of OJEMDA or our product candidates in the most efficient manner or at all; and

• if a future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

If we establish one or more collaborations, all of the risks relating to product development, marketing authorization and commercialization described herein would also apply to the activities of any such future collaborators.

The loss of any large customer, or any cancellation or delay of a significant purchase by a large customer, could reduce our net sales and harm our operating results.

We have received a substantial portion of our revenue from a limited number of customers. For example, for the six months ended June 30, 2024, two individual customers accounted for 98% of our total net product revenue, with these individual customers representing 61% and 37% of total net product revenue. As of June 30, 2024, two customers accounted for 98% of the accounts receivable balance, with these individual customers representing 59% and 39% of the accounts receivable balance.

We cannot provide any assurances that we will retain our current customers or groups of customers, that they will maintain their current or forecasted demand for our products, or that we will be able to attract and retain additional customers in the future. If for any reason we were to lose our ability to sell to a specific group or class of customers, we could experience a significant reduction in revenue or loss of market share, which would adversely impact our operating results.

Risks Related to Employee Matters and Our Operations

Our future success depends on our ability to retain our executive officers and key employees and to attract, retain and motivate qualified personnel and manage our human capital.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract, motivate and retain highly qualified managerial, scientific, medical and commercial personnel. We are highly dependent on the development and management expertise of Jeremy Bender, Ph.D., M.B.A., our Chief Executive Officer, and Samuel Blackman, M.D., Ph.D., our Head of Research and Development, as well as the other members of our management team, other key employees and advisors. We currently do not maintain key person insurance on these individuals. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time.

Our industry has experienced a high rate of turnover in recent years. Our ability to compete in the highly competitive pharmaceuticals industry depends upon our ability to attract, retain and motivate highly skilled and experienced personnel with scientific, clinical, regulatory, manufacturing, quality, commercial and management skills and experience.

We largely conduct our operations in the greater San Francisco Bay Area, a region that is home to other pharmaceutical companies as well as many academic and research institutions, resulting in fierce competition for qualified personnel. We may not be able to attract or retain qualified personnel in the future due to the intense competition for a limited number of qualified personnel among pharmaceutical companies. Many of the other pharmaceutical companies against which we compete have greater financial and other resources, different risk profiles and a longer history in the industry than we do. Our competitors may provide higher compensation, more diverse opportunities and/or better opportunities for career advancement. In addition, as our business changes, key personnel may not want to work for a larger, commercial enterprise. Any or all of these competing factors may limit our ability to continue to attract and retain high quality personnel, which could negatively affect our ability to successfully develop and commercialize OJEMDA or our product candidates and to grow our business and operations as currently contemplated. We have adopted a greater level of flexibility in our recruiting practices to attract and hire candidates outside of the San Francisco Bay Area, which is intended to increase retention but could have a negative impact on employee engagement, resulting in greater employee turnover.

We will need to grow the size and capabilities of our organization, and we may experience difficulties in managing this growth.

We had 169 full-time employees as of June 30, 2024. We expect significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical development, clinical operations, manufacturing, regulatory affairs, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth and with developing sales, marketing and distribution infrastructure, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources.

Further, we currently rely, and for the foreseeable future will continue to rely, in substantial part on certain third-party contract organizations, advisors and consultants to provide certain services, including assuming substantial responsibilities for the conduct of our clinical trials and the manufacture of OJEMDA, pimasertib, DAY301 or any future product candidates. We cannot assure you that the services of such third-party contract organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by our vendors or consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing authorization of pimasertib or DAY301 or any future product candidates or otherwise advance our business. We cannot assure you that we will be able to properly manage our existing vendors or consultants or find other competent outside vendors and consultants on economically reasonable terms, or at all.

If we are not able to effectively manage growth and expand our organization, we may not be able to successfully implement the tasks necessary to further develop and commercialize OJEMDA, pimasertib, DAY301, our other pipeline product candidates or any future product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our employees, clinical trial investigators, CROs, CMOs, consultants, vendors and any future commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees and third parties that we rely on, including, clinical trial investigators, CROs, CMOs, consultants, vendors and any future commercial partners. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) FDA regulations or those of comparable foreign regulatory authorities, including those laws that require the reporting of true, complete and accurate information, (ii) manufacturing (e.g., cGMP) and clinical practice (e.g., GCP) standards, (iii) federal and state health and data privacy, security, fraud and abuse, government price reporting, transparency reporting requirements and other healthcare laws and regulations in the United States and abroad, (iv) sexual harassment and other workplace misconduct, or (v) laws that require the true, complete and accurate reporting of financial information or data. In particular, research, sales, marketing and business arrangements in our industry are subject to a wide variety of laws and regulations that are intended to prevent fraud, misconduct, kickbacks and other abusive practices. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation.

We have adopted a code of conduct applicable to all of our employees, as well as a disclosure program and other applicable policies and procedures, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations.

Further, with respect to third parties, third parties are not our employees, and except for remedies available to us under our agreements, we have limited ability to control resources that any such third party will devote to our preclinical studies or our clinical trials. The third parties we rely on for these services may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting drug development activities, which could affect their performance on our behalf.

Our reliance on third parties for drug development activities means that we will have less direct control over the conduct, timing and completion of studies and the management of data generated from such studies. Nonetheless, we remain responsible for ensuring that our studies and trials are conducted in accordance with applicable protocol, legal and regulatory requirements and scientific standards. In other words, our reliance on third parties does not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the investigational plan and relevant protocols and that any such trial complies with GCP standards. If we or any of our CROs or any clinical trial sites fail to comply with applicable GCP requirements, the clinical data generated in those trials may be deemed unreliable. This may cause the FDA or other comparable foreign regulatory authorities to require us to perform additional clinical trials before approving our marketing applications. If any of the third parties we rely on violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws, or other laws, actions may be instituted against us.

If any actions based on our conduct, our employees' conduct or third-party conduct are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare, Medicaid and other federal healthcare programs, injunctions, private actions brought by individual whistleblowers in the name of the government, debarment or refusal to allow us to enter into government contracts, contractual damages, reputational harm, diminished profits and future earnings, additional integrity reporting and oversight obligations and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Additionally, there are risks that the third parties we rely on could become disqualified, debarred, suspended or otherwise penalized by the FDA or other comparable foreign regulatory authorities for violations of applicable regulatory requirements, in which case we may need to engage a substitute and may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

If our security measures are compromised, or our information technology systems or those of our CROs, CMOs, vendors, contractors, consultants or other third-party partners fail or suffer security breaches, cyber-attacks, loss or leakage of data or other disruptions, this could result in a material disruption of our development programs, compromise sensitive information related to our business or other personal information or prevent us from accessing critical information, potentially exposing us to liability, harm our reputation or otherwise adversely affecting our business.

In the ordinary course of business, we may collect, process, store and transmit proprietary, confidential and sensitive information (including but not limited to intellectual property, trade secrets, proprietary business information, personal information and protected health information, or PHI). It is critical that we do so in a secure manner to maintain the confidentiality, integrity and availability of such information. We depend on information technology and telecommunications systems for significant elements of our operations and we have installed, and expect to expand, a number of enterprise software systems that affect a broad range of business processes and functional areas, including, for example, systems handling human resources, financial reporting and controls, customer relationship management, regulatory compliance and other infrastructure operations. We face a number of risks relative to protecting this critical information, including loss of access risk, inappropriate use or disclosure, inappropriate modification and the risk of our being unable to adequately monitor, audit and modify our controls over our critical information. This risk extends to the third parties with whom we work, as we rely on a number of third parties to operate our critical business systems and process confidential, proprietary and sensitive information.

Despite the implementation of security measures, given the size, complexity and increasing amounts of proprietary, sensitive and confidential information maintained by our internal information technology systems and those of our CROs, CMOs, vendors, contractors, consultants and other third-party partners are potentially vulnerable to breakdown, service interruptions, system malfunction, accidents by our personnel or third-party partners, natural disasters, terrorism, global pandemics, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our personnel or those of our CROs, CMOs, vendors, contractors, consultants, business partners and/or other third-party partners, or from cyber-attacks by malicious third parties (including through viruses, worms, malicious code, malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and the confidentiality, integrity and availability of information), which may compromise our system infrastructure, or that of our CROs, CMOs, vendors, contractors, consultants and other third-party partners, or lead to data leakage.

The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, viruses, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. The increase of "work from home" in recent years has generally increased the attack surface available for exploitation, as more companies and individuals work online and work remotely, and as such, the risk of a cybersecurity incident potentially occurring, and our investment in risk mitigations against such an incident, is increasing. For example, there has been an increase in phishing and spam emails as well as social engineering attempts from "hackers" hoping to use the increase of remote work to their advantage. We may not be able to anticipate all types of security threats, nor may we be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals

change frequently, may not be recognized until launched and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or those of our CROs, CMOs, vendors, contractors, consultants and other third-party partners, or inappropriate disclosure of confidential, sensitive or proprietary information, we could incur liability and reputational damage and the further development and commercialization of OJEMDA, pimasertib, DAY301 or any future product candidates could be delayed. Any breach, loss or compromise of proprietary, sensitive or confidential information may also subject us to civil fines and penalties, including under HIPAA, and other relevant state and federal privacy laws in the United States. For example, the California Consumer Privacy Act of 2018, or the CCPA, as amended by the California Privacy Rights Act, or the CPRA, imposes a private right of action for security breaches that could lead to some form of remedy including regulatory scrutiny, fines, private right of action settlements, and other consequences.

The costs related to significant security breaches or disruptions could be material and exceed the limits of the cybersecurity insurance we maintain against such risks. If the information technology systems of our CROs, CMOs, vendors, contractors, consultants and other third-party partners become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring.

We cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, breaches in our systems, or those of our CROs, CMOs, vendors, contractors, consultants and other third-party partners, or other cyber incidents that could have a material adverse effect upon our reputation, business, operations or financial condition. For example, if such an event were to occur and cause interruptions in our operations, or those of our third-party CROs, CMOs, vendors and other contractors and consultants, it could result in a material disruption of our programs and the development of our product candidates could be delayed. In addition, the loss of clinical trial data for OJEMDA, pimasertib, DAY301, or any other product candidates could result in delays in our marketing authorization efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of our internal information technology systems or those of our third-party CROs, CMOs, vendors and other contractors and consultants, or security breaches could result in the loss, misappropriation and/or unauthorized access, use or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information and personal information), which could result in financial, legal, business and reputational harm to us. For example, any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding our clinical trial subjects or personnel, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

We are required to comply with laws, rules and regulations that require us to maintain the security of personal information. We may have contractual and other legal obligations to notify relevant stakeholders of security breaches. Failure to prevent or mitigate cyber-attacks could result in the unauthorized access to sensitive, confidential or proprietary information. Most jurisdictions have enacted laws requiring companies to notify individuals, regulatory authorities and others of security breaches involving certain types of data. In addition, our agreements with CROs, CMOs, vendors, contractors, consultants and other third-party partners may require us to notify them in the event of a security breach. Such mandatory disclosures are costly, could lead to negative publicity, may cause our customers to lose confidence in the effectiveness of our security measures and require us to expend significant capital and other resources to respond to and/or alleviate problems caused by the actual or perceived security breach.

The costs to respond to a security breach and/or to mitigate any security vulnerabilities that may be identified could be significant, our efforts to address these issues may not be successful and these issues could result in interruptions, delays, negative publicity, loss of customer trust or diminished use of our products, as well as other harms to our business and our competitive position. Remediation of any potential security breach may involve significant time, resources and expenses. Any security breach may result in regulatory inquiries, litigation or other investigations, and can affect our financial and operational condition.

Litigation resulting from security breaches may adversely affect our business. Unauthorized access to our systems, networks or physical facilities could result in litigation with our customers or other relevant stakeholders. These proceedings could force us to spend money in defense or settlement, divert management’s time and attention, increase our costs of doing business or adversely affect our reputation.

We may not have adequate insurance coverage for security incidents or breaches, including fines, judgments, settlements, penalties, costs, attorney fees and other impacts that arise out of incidents or breaches. The successful assertion of one or more large claims against us that exceeds available insurance coverage, or results in changes to insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage and coverage for errors and omissions will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim. Our risks are likely to increase as we continue to expand, grow our customer base and process, store and transmit increasingly large amounts of proprietary and sensitive data.

We are subject to stringent and changing laws, regulations and standards, and contractual obligations related to privacy, data protection and data security. The actual or perceived failure to comply with such obligations could lead to government enforcement actions (which could include civil or criminal penalties), fines and sanctions, private litigation and/or adverse publicity and could negatively affect our operating results and business.

We and third parties who we work with are or may become subject to numerous domestic and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security), the scopes of which are changing, subject to differing applications and interpretations, and may be inconsistent among countries, or conflict with other rules. We are or may become subject to the terms of contractual obligations related to privacy, data protection and data security. The actual or perceived failure by us or related third parties to comply with such obligations could increase our compliance and operational costs, expose us to regulatory scrutiny, actions, fines and penalties, result in reputational harm, lead to a loss of customers, result in litigation and liability and otherwise cause a material adverse effect on our business, financial condition and results of operations.

In the United States, numerous federal and state laws and regulations, including federal health information privacy and security laws, federal and state data breach notification laws, state health information privacy laws and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act) that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain protected health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, as amended by HITECH. Depending on the facts and circumstances, we could be subject to civil and criminal penalties if we obtain, use or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Washington state recently passed the My Health My Data Act, which is focused on the collection of consumer health data. The My Health My Data Act has a broader scope than HIPAA and includes a private right of action. The My Health Data Act became effective on March 31, 2024 and there may be substantial regulatory action and litigation associated with the My Health Data Act.

The state of California recently enacted the CCPA, which creates new individual privacy rights for California consumers and places increased privacy and data security obligations on entities handling personal information of consumers or households. The CCPA, in effect since January 1, 2020, and most recently amended by the CPRA, is now in effect as of January 1, 2023 and enforced as of July 1, 2023, subject to the regulations promulgated through a newly created enforcement agency called the California Privacy Protection Agency, or the CPPA. The CCPA gives California residents expanded privacy rights, including the right to request correction, access and deletion of their personal information, the right to opt out of certain personal information sharing and the right to receive detailed information about how their personal information is processed, including by California residents' employers. The CCPA and CPRA provide for civil penalties and a private right of action for data breaches that is expected to increase data breach litigation. The CCPA and CPRA may increase our compliance costs and potential liability. The CCPA has prompted several proposals for new federal and state-level privacy legislation which, if enacted, could increase our potential liability and compliance costs, and adversely affect our business.

Foreign data protection laws, including Regulation 2016/679, known as the General Data Protection Regulation, or GDPR, may apply to personal information (including health-related data) obtained from individuals in the European Economic Area, or the EEA, and Switzerland. The GDPR, and its implementing legislation across the EU, imposes strict obligations on businesses, including requiring changes to informed consent practices and more detailed notices for clinical trial subjects and investigators, requiring limitations on data processing, establishing a legal basis for processing personal information, notification of data processing obligations, notification of security incidents to appropriate data protection authorities or data subjects, protecting the security and confidentiality of the personal information, and establishing means for data subjects to exercise rights in relation to their personal information. The GDPR subjects noncompliant companies to fines of up to the greater of 20 million Euros or 4% of their global annual revenues, potential bans on processing of personal information (including clinical trials), and private litigation. To the extent applicable, the GDPR will increase our responsibility and liability in relation to personal information that we process, and we may be required to put in place additional mechanisms and expend additional time and resources to ensure compliance with the EU data protection rules. Additionally, the UK implemented the Data Protection Act effective in May 2018 and statutorily amended in 2019, that substantially implements the GDPR and contains provisions, including UK-specific derogations, for how GDPR is applied in the UK. Changes in these legislations may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment in resources for compliance programs, could impact strategies and availability of previously useful data, and could result in increased compliance costs and/or changes in business practices and policies. In addition, supervisory authorities in the EEA, Switzerland, and the UK have enforced data protection legislation inconsistently, which may result in us having to spend additional resources in order to comply with rules and guidance applicable only in certain, local jurisdictions.

Further, European data protection laws generally prohibit the transfer of personal information to countries outside of the EEA, UK and Switzerland, such as the United States, which are not considered by the European Commission to provide an adequate level of data protection. Switzerland has adopted similar restrictions. Although there are legal mechanisms to allow for the transfer of personal information from the EEA, UK, and Switzerland to the United States and other countries, they are or may become subject to legal challenges that, if successful, could invalidate these mechanisms, restrict our ability to process personal information of Europeans outside of Europe and adversely impact our business. For example, in July 2020, the Court of Justice of the European Union, or CJEU,

invalidated the EU-U.S. Privacy Shield, which enabled the transfer of personal information from EU to the U.S. for companies that had self-certified to the Privacy Shield on the grounds that the EU-U.S. Privacy Shield failed to offer adequate protections to EU personal information transferred to the United States. While the CJEU did not invalidate the use of other data transfer mechanisms, such as the Standard Contractual Clauses, the decision has led to uncertainty regarding the use of such mechanisms for data transfers to the United States, and the CJEU made clear that reliance on Standard Contractual Clauses alone may not necessarily be sufficient in all circumstances. The European Data Protection Board, or EDPB, issued additional guidance regarding the CJEU's decision on November 11, 2020 which imposes higher burdens on the use of data transfer mechanisms, such as the Standard Contractual Clauses, for cross-border data transfers. In June 2021, the European Commission adopted new Standard Contractual Clauses under the GDPR for transfers of personal data outside the EU to countries that the European Commission has not deemed to provide an adequate level of protection for such personal data. Effective July 10, 2023, the new EU-U.S. Data Privacy Framework, or the DPF, has been recognized as adequate under EU law to allow transfers of personal data from the EU to certified companies in the United States. However, the DPF is subject to further legal challenges which could cause the legal requirements for personal data transfers from the EU to the United States to become uncertain once again. While the DPF does not apply to the UK, on October 12, 2023, the UK government adopted an adequacy decision concluding that the United States ensures an adequate level of protection transferred from the UK to the United States under the UK Extension to the EU-U.S. Data Privacy Framework, or the UK DPF. We anticipate a similar adequacy decision from the Swiss government, or Swiss DPF. Both the UK DPF and the Swiss DPF could also be contested or otherwise affected by any challenges to the EU-U.S. DPF. If we cannot implement a valid compliance mechanism for cross-border data transfers, we may face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal data from Europe or other foreign jurisdictions. In the EU and other markets, potential new rules and restrictions on the flow of data across borders could increase the cost and complexity of doing business in those regions.

In addition, further to the UK's exit from the EU on January 31, 2020, the GDPR ceased to apply in the UK at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the United Kingdom's European Union (Withdrawal) Act 2018 incorporated the GDPR (as it existed on December 31, 2020 but subject to certain UK-specific amendments) into UK law, referred to as the UK GDPR. The UK GDPR and the UK Data Protection Act 2018 set out the UK's data protection regime, which is independent from but aligned to the EU's data protection regime. Non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher. With respect to transfers of personal data from the EU to the United Kingdom, on June 28, 2021 the European Commission issued an adequacy decision in respect of the UK's data protection framework, enabling data transfers from EU member states to the UK to continue without requiring organizations to put in place contractual or other measures in order to lawfully transfer personal data between the territories. While it is intended to last for at least four years, the European Commission may unilaterally revoke the adequacy decision at any point, and if this occurs it could lead to additional costs and increase our overall risk exposure.

Other countries, including China, Brazil, Australia and Japan, for example, have adopted certain legal requirements for local storage and processing of data and cross-border transfers of personal information, any and all of which could increase the cost and complexity of conducting preclinical testing and clinical trials or delivering our future products, if any, and operating our business. These obligations may be interpreted and applied in a manner that is inconsistent from one jurisdiction to another and may conflict with other requirements or our practices.

Further, on July 26, 2023, the SEC adopted new cybersecurity disclosure rules for public companies that require disclosure regarding cybersecurity risk management (including the board's role in overseeing cybersecurity risks, management's role and expertise in assessing and managing cybersecurity risks and processes for assessing, identifying and managing cybersecurity risks) in annual reports on Form 10-K. These new cybersecurity disclosure rules also require the disclosure of material cybersecurity incidents by Form 8-K, within four business days of determining an incident is material.

We are or may become subject to the terms of external and internal privacy and security policies, representations, certifications and publications related to privacy and security.

Compliance with domestic and foreign privacy, data security and data protection laws, regulations and contractual and other obligations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. The actual or perceived failure to comply with domestic and foreign privacy, data privacy and data protection laws and regulations could result in government enforcement actions (which could include civil, criminal and administrative penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with privacy, data security and data protection laws or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could harm our business.

Investors' expectations of our performance relating to environmental, social and governance factors may impose additional costs and expose us to new risks.

There is an increasing focus from certain regulators, investors, employees, users and other stakeholders concerning corporate responsibility, specifically related to ESG matters both in the United States and internationally. Some investors may use these non-financial performance factors to guide their investment strategies and, in some cases, may choose not to invest in us if they believe our policies and actions relating to corporate responsibility are inadequate. We may face reputational damage in the event that we do not meet the ESG standards set by various constituencies.

Further, ESG initiatives, goals or commitments could be difficult to achieve or costly to implement. If our competitors' corporate social responsibility performance is perceived to be better than ours, potential or current investors may elect to invest with our competitors instead. Moreover, California recently adopted two new climate-related bills, which require companies doing business in California that meet certain revenue thresholds to publicly disclose certain greenhouse gas emissions data and climate-related financial risk reports, and compliance with such requirements could require significant effort and resources. Additionally, in March 2024, the SEC enacted comprehensive climate change disclosure rules, although the SEC has since issued an order to stay the rules pending the completion of judicial review of multiple petitions challenging the rules. Our business may face increased scrutiny related to these activities and our related disclosures, including from the investment community, and our failure to achieve progress or manage the dynamic public sentiment and legal landscape in these areas on a timely basis, or at all, could adversely affect our reputation, business, and financial performance.

We or the third parties upon whom we depend may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our current operations are primarily located in the San Francisco Bay Area. Any unplanned event, such as earthquake, flood, fire, explosion, extreme weather conditions, medical epidemic or pandemic, power shortage, telecommunication failure or other natural or man-made accident or incident that results in our being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. In addition, the long-term effects of climate change on general economic conditions and the pharmaceutical industry in particular are unclear, and may heighten or intensify existing risk of natural disasters. Loss of access to these facilities may result in increased costs, delays in the development of OJEMDA or our product candidates or interruption of our business operations, and have a material adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure such as our research facilities or the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Changes in tax laws or regulations that are applied adversely to us may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Tax Cuts and Jobs Act of 2017, or the Tax Cuts and Jobs Act, enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Cuts and Jobs Act may affect us, and certain aspects of the Tax Cuts and Jobs Act could be repealed or modified in future legislation. For example, the CARES Act modified certain provisions of the Tax Cuts and Jobs Act. In addition, it is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act, the CARES Act, or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Cuts and Jobs Act, the CARES Act or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. Unused losses incurred in taxable years beginning on or prior to December 31, 2017, will carry forward to offset future taxable income, if any, until such unused losses expire. Under the Tax Cuts and Jobs Act, as modified by the CARES Act,

unused U.S. federal net operating losses generated in tax years beginning after December 31, 2017, will not expire and may be carried forward indefinitely but the deductibility of such federal net operating losses in taxable years beginning after December 31, 2020, is limited to 80% of current year taxable income. It is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act or the CARES Act. In addition, both our current and our future unused losses and other tax attributes may be subject to limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, if we undergo, or have undergone, an "ownership change," generally defined as a greater than 50 percentage point change (by value) in our equity ownership by certain stockholders over a three-year period. We have not completed a Section 382 study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since our formation due to the complexity and cost associated with such a study and the fact that there may be additional ownership changes in the future. As a result, our net operating loss carryforwards generated in taxable years beginning on or before December 31, 2017, may expire prior to being used, and the deductibility of our net operating loss carryforwards generated in taxable years beginning after December 31, 2017 may be limited, and, if we undergo an ownership change (or if we previously underwent such an ownership change), our ability to use all of our pre-change net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) to offset our post-change income or taxes may be limited. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of net operating losses is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use all or a material portion of our net operating losses and other tax attributes, which could adversely affect our future cash flows.

We have engaged, and will continue to engage, in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

We have engaged in strategic transactions, for instance with affiliates of Takeda Pharmaceutical Company Limited, Viracta Therapeutics, Inc., Merck KGaA, Darmstadt, Germany and MabCare, and from time to time, we may consider further strategic transactions, such as acquisitions of companies, businesses or assets and out-licensing or in-licensing of products, product candidates (such as DAY301) or technologies. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near term or long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- write-downs of assets or goodwill or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations, systems and personnel of any acquired businesses with our operations, systems and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection or other necessary rights for our products and technology, or if the scope of the patent protection obtained is not sufficiently broad or our rights under our patents (owned, co-owned or licensed) is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our products and technology may be adversely affected.

Our commercial success depends in part on our ability to obtain and maintain proprietary or intellectual property protection in the United States and other countries for OJEMDA and our current product candidates and future products, as well as our core technologies, including our manufacturing know-how. We strive to protect and enhance the proprietary technology, inventions and improvements that are commercially important to the development of our business by seeking, maintaining and defending our intellectual property, whether developed internally or licensed from third parties. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen and maintain our proprietary position in the field of

cancer drug development. Additionally, we intend to rely on regulatory protection afforded through rare drug designations, data exclusivity and market exclusivity as well as patent term extensions, where available.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. The degree of patent protection we require to successfully compete in the marketplace may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our own or licensed patent applications will mature into issued patents, and cannot provide any assurances that any such patents, if issued, will include claims with a scope sufficient to protect OJEMDA and our current and future product candidates or otherwise provide any competitive advantage. Additionally, patents can be enforced only in those jurisdictions in which the patent has issued. Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first nonprovisional U.S. filing. The natural expiration of a patent outside of the United States varies in accordance with provisions of applicable local law, but is generally 20 years from the earliest local filing date. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized.

Moreover, our exclusive licenses may be subject to field restrictions and retained rights, which may adversely impact our competitive position. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Significant Agreements.” Our licensed patent portfolio may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing products similar to OJEMDA and our product candidates, including generic versions of such products. In addition, the patent portfolio licensed to us is, or may be, licensed to third parties outside our licensed field, and such third parties may have certain enforcement rights. Thus, patents licensed to us could be put at risk of being invalidated or interpreted narrowly in litigation filed by or against another licensee or in administrative proceedings brought by or against another licensee in response to such litigation or for other reasons.

Other parties have developed technologies that may be related or competitive to our own and such parties may have filed or may file patent applications, or may have received or may receive patents, claiming inventions that may overlap or conflict with those claimed in our own patent applications or issued patents. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and in other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether the inventors of our patents and applications were the first to make the inventions claimed in those patents or pending patent applications, or that they were the first to file for patent protection of such inventions. Further, we cannot assure you that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent from issuing from a pending patent application. As a result, the issuance, scope, validity and commercial value of our patent rights cannot be predicted with any certainty. Further, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize OJEMDA or our current or future product candidates.

In addition, the patent prosecution process is expensive and time-consuming, and we or our licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, the scope of the claims initially submitted for examination may be significantly narrowed by the time they issue, if at all. It is also possible that we or our licensors will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We cannot provide any assurances that we will be able to pursue or obtain additional patent protection based on our research and development efforts, or that any such patents or other intellectual property we generate will provide any competitive advantage. Moreover, we do not have the right to control the preparation, filing and prosecution of patent applications, or to control the maintenance of the patents, covering technology that we license from third parties. Therefore, these patents and applications may not be filed, prosecuted or maintained in a manner consistent with the best interests of our business.

Even if we acquire patent protection that we expect should enable us to maintain competitive advantage, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability. Third parties, including competitors, may challenge the inventorship, scope, validity or enforceability thereof, which may result in such patents being narrowed, invalidated or held unenforceable. If issued, our patents may be challenged in patent offices in the United States and abroad, or in court. For example, we may be subject to a third-party submission of prior art to the U.S. Patent and Trademark Office, or USPTO, challenging the validity of one or more claims of our patents, once issued. Such submissions may also be made prior to a patent’s issuance, precluding the granting of a patent based on one of our patent applications. We may become involved in opposition, reexamination, *inter partes* review, post-grant review, derivation, interference or similar proceedings in the United States or abroad challenging the claims of our patents, once issued. Furthermore, patents may be challenged in court, once issued. Competitors may claim that they invented the inventions claimed in such patents or patent applications prior to the inventors of our patents, or may have filed patent applications before the inventors of our patents did. A competitor may also claim that we are infringing its patents and that we therefore cannot practice our technology as claimed under our patent applications and patents, if issued. As a result, one or more claims of our patents may be narrowed or invalidated. In litigation, a competitor could claim that our patents, if issued, are not valid for a number of reasons. If a court agrees, we would lose our rights to those challenged patents.

Even if they are unchallenged, our patents and pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our patents by developing similar or alternative technologies or therapeutics in a non-infringing manner. For example, even if we have a valid and enforceable patent, we may not be able to exclude others from practicing our invention if the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. If the patent protection provided by the patents and patent applications we hold or pursue with respect to OJEMDA or our product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize OJEMDA or our product candidates could be negatively affected, which would harm our business. Certain regulatory exclusivities may be available, however, the scope of such regulatory exclusivities is subject to change and may not provide us with adequate and continuing protection sufficient to exclude others from commercializing products similar to OJEMDA and our product candidates.

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical products or product candidates would be adversely affected.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications and those of our licensors may not result in patents being issued which protect our product candidates or which effectively prevent others from commercializing competitive product candidates.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own or in-license in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Any patents that we own or in-license may be challenged or circumvented by third parties or may be narrowed or invalidated as a result of challenges by third parties. Consequently, we do not know whether our product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents or the patents of our licensors by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents or the patents of our licensors may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant review and *inter partes* review, or other similar proceedings challenging our owned patent rights. An adverse determination in any such submission, proceeding or litigation could jeopardize patent term adjustment or otherwise reduce patent term, reduce the scope of or invalidate or render unenforceable, our patent rights, or allow third parties to commercialize our product candidates and compete directly with us, without payment to us. Moreover, our patents or the patents of our licensors may become subject to post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our priority of invention or other features of patentability with respect to our patents and patent applications and those of our licensors. Such challenges may result in loss of patent rights, loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our patents and patent applications or the patents and patent applications of our licensors is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Furthermore, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own patented product and practicing our own patented technology.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

• others may be able to develop products that are similar to OJEMDA and our product candidates but that are not covered by the claims of the patents that we own or license;

• we or our licensors or collaborators might not have been the first to make the inventions covered by the issued patents or patent application that we own or license;

• we or our licensors or collaborators might not have been the first to file patent applications covering certain of our inventions;

• others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;

• it is possible that the pending patent applications we own or license will not lead to issued patents;

• issued patents that we own or license may be held invalid or unenforceable, as a result of legal challenges by our competitors;

• our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

• we may not develop additional proprietary technologies that are patentable;

• the patents of others may have an adverse effect on our business;

• we may fail to adequately protect and police our trademarks and trade secrets; and

• we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, it could significantly harm our business, results of operations and prospects.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts.

Our commercial success depends in part on avoiding infringement of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our product candidates and products that may be approved in the future, or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry, including patent infringement lawsuits, oppositions, reexaminations, *inter partes* review proceedings and post grant review proceedings before the USPTO and/or corresponding foreign patent offices. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates.

There may also be patent applications that, if issued as patents, could be asserted against us. Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. patent applications that will not be filed outside the United States can remain confidential until patents issue. Therefore, patent applications covering our product candidates could have been filed by third parties without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates and their uses or manufacturing processes. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history and can involve other factors such as expert opinion. Our interpretation of the relevance or the scope of claims in a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. Further, we may incorrectly determine that our product candidates and their uses and manufacturing processes are not covered by a third-party patent or may incorrectly predict whether a third-party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Third-party intellectual property right holders may also actively bring infringement or other intellectual property-related claims against us, even if we have received patent protection for our product candidates and the relevant uses and processes.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published, we may be unaware of third-party patents that may be infringed by commercialization of any of our product candidates, and we cannot be certain that we were the first to file a patent application related to a product candidate or technology. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. There is also no assurance that there is not prior art of which we are aware, but which we do not believe is relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our products that may be approved in the future, or impair our competitive position. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Any claims of patent infringement asserted by third parties would be time consuming and could:

• result in costly litigation that may cause negative publicity;

• divert the time and attention of our technical personnel and management;

• cause development delays;

• prevent us from commercializing OJEMDA or any of our product candidates until the asserted patent expires or is held finally invalid or not infringed in a court of law;

• require us to develop non-infringing technology, which may not be possible on a cost-effective basis;

• subject us to significant liability to third parties; or

• require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all, or which might be non-exclusive, which could result in our competitors gaining access to the same technology.

Although no third party has asserted a claim of patent infringement against us as of June 30, 2024, others may hold proprietary rights that could prevent OJEMDA or our product candidates from being marketed. It is possible that a third-party may assert a claim of patent infringement directed at OJEMDA or our product candidates. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to OJEMDA or our product candidates, treatment indications, or processes could subject us to significant liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license to manufacture or market OJEMDA or our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Moreover, even if we or our current and/or future strategic partners were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we cannot be certain that we could redesign OJEMDA, our product candidates, treatment indications, or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing our product candidates, which could harm our business, financial condition and operating results. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing OJEMDA or our product candidates and technology.

Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Some of our current product candidates and research programs are licensed from third parties. If these license agreements are terminated or interpreted to narrow our rights, our ability to advance OJEMDA and our current product candidates or develop new product candidates based on these technologies will be materially adversely affected.

We now depend on, at least in part, Viracta Therapeutics, Inc., Takeda Pharmaceutical Company Limited, Dana Farber Cancer Institute, Millennium Pharmaceuticals, Inc., Merck KGaA, Darmstadt, Germany and MabCare and will continue to depend on Viracta Therapeutics, Inc., Takeda Pharmaceutical Company Limited, Dana Farber Cancer Institute, Millennium Pharmaceuticals, Inc. and Merck KGaA, Darmstadt, Germany and MabCare and on licenses and sublicenses from other third parties, as well as potentially on other strategic relationships with third parties, for the research, development, manufacturing and commercialization of OJEMDA and our current product candidates. If any of our licenses or relationships or any in-licenses on which our licenses are based are terminated or breached, we may:

• lose our rights to develop and market OJEMDA or our current product candidates;

• lose patent or trade secret protection for OJEMDA or our current product candidates;

• experience significant delays in the development or commercialization of OJEMDA or our current product candidates;

• not be able to obtain any other licenses on acceptable terms, if at all; or

• incur liability for damages.

Additionally, even if not terminated or breached, our intellectual property licenses or sublicenses may be subject to disagreements over contract interpretation which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations.

If we experience any of the foregoing, it could have a materially adverse effect on our business and could force us to cease operations which could cause you to lose all of your investment.

If we breach our license agreements, it could have a material adverse effect on our commercialization efforts for OJEMDA and our product candidates.

If we breach any of the agreements under which we license the use, development and commercialization rights to OJEMDA and our product candidates or technology from third parties, we could lose license rights that are important to our business. Or if we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

OJEMDA and our current lead product candidates are protected by, among other intellectual property rights, patents and patent applications we co-own and exclusively in-license from Viracta Therapeutics, Inc. (f/k/a Sunesis Pharmaceuticals, Inc.). OJEMDA and our current lead product candidates and pipeline and our anticipated near-term pipeline may include technologies, licensed from other third parties, including, for example, Merck KGaA, Darmstadt, Germany. Further, pursuant to the MabCare License Agreement, we have the exclusive right to develop, manufacture and commercialize DAY301 worldwide, excluding Greater China.

Under the license agreements, we are subject to various obligations, including diligence obligations such as development and commercialization obligations, as well as potential royalty payments and other obligations. If we fail to comply with any of these obligations or otherwise breach our license agreements, our licensors may have the right to terminate the applicable license in whole or in part. Generally, the loss of any one of our current licenses, or any other license we may acquire in the future, could harm our business, prospects, financial condition and results of operations.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other intellectual property rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of OJEMDA and our product candidates, and what activities satisfy those diligence obligations;
- the priority of invention of patented technology;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- whether and the extent to which inventors are able to contest the assignment of their rights to our licensors.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms or at all, we may be unable to successfully develop and successfully commercialize OJEMDA and the affected product candidates. In addition, if disputes arise as to ownership of licensed intellectual property, our ability to pursue or enforce the licensed patent rights may be jeopardized. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize our products could suffer.

In addition, the agreements under which we license intellectual property or technology from third parties, including our licenses with Viracta Therapeutics, Inc., Takeda Pharmaceutical Company Limited, Dana Farber Cancer Institute, Millennium Pharmaceuticals, Inc., Merck KGaA, Darmstadt, Germany and MabCare are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we license prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

In spite of our best efforts, our licensors might conclude that we materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek marketing authorization of, and to market, products identical to ours. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

While we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual

property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

In the future, we may need to obtain additional licenses of third-party technology that may not be available to us or are available only on commercially unreasonable terms, and which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated.

We seek to expand our product candidate pipeline in part by in-licensing the rights to key technologies. The future growth of our business will depend in part on our ability to in-license or otherwise acquire the rights to additional product candidates or technologies. We cannot assure you that we will be able to in-license or acquire the rights to any product candidates or technologies from third parties on acceptable terms or at all.

Other companies and academic institutions may also have filed or are planning to file patent applications potentially relevant to our business. From time to time, in order to avoid infringing these third-party patents, we may be required to license technology from third parties to further develop or commercialize our existing or future product candidates. Should we be required to obtain licenses to any third-party technology, including any such patents required to manufacture, use or sell our existing or future product candidates, such licenses may not be available to us on commercially reasonable terms, or at all. The inability to obtain any third-party license required to develop or commercialize any of our existing or future product candidates could cause us to abandon any related efforts, which could seriously harm our business and operations.

The in-licensing and acquisition of these technologies is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire product candidates or technologies that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to license rights to us. Furthermore, we may be unable to identify suitable product candidates or technologies within our area of focus. If we are unable to successfully obtain rights to suitable product candidates or technologies, our business, financial condition and prospects could suffer.

We may be involved in lawsuits to protect or enforce our own patents or our licensors' patents, which could be expensive, time consuming and unsuccessful. Further, our own issued patents or our licensors' patents could be found invalid or unenforceable if challenged in court.

Competitors may infringe our intellectual property rights. To prevent infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in a patent infringement proceeding, a court may decide that a patent we own or in-license is not valid, is unenforceable and/or is not infringed. If we or any of our collaborators were to initiate legal proceedings against a third-party to enforce a patent directed at OJEMDA or one of our product candidates, the defendant could counterclaim that our patent or the patent of our licensors is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of sufficient written description, non-enablement or obviousness-type double patenting. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution.

Third parties may also raise similar invalidity claims before the USPTO or patent offices abroad, even outside the context of litigation. Such mechanisms include re-examination, *inter partes* review proceedings, post grant review proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). The outcome following legal assertions of invalidity and/or unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our licensors and the patent examiners are unaware during prosecution. There is also no assurance that there is not prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim in our patents and patent applications or the patents and patent applications of our licensors, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our technology, or any product candidates that we may develop. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects.

In addition, if the breadth or strength of protection provided by our patents and patent applications or the patents and patent applications of our licensors is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating costs and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or

proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common shares to decline.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions and other interim proceedings or developments in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing product candidates, approved products, programs or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our product candidates, which could have a material adverse effect on our business.

Derivation proceedings may be necessary to determine priority of inventions, and an unfavorable outcome may require us to cease using the related technology or to attempt to license rights from the prevailing party.

Derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees from their regular responsibilities. In addition, the uncertainties associated with such proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our development programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our product candidates to market.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders, or it may be otherwise impractical or undesirable to enforce our intellectual property against some third parties. Our competitors or other third parties may be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our product development, in-license needed technology or enter into development partnerships that would help us bring OJEMDA and our product candidates to market.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and/or those of our licensors and the enforcement or defense of our issued patents and/or those of our licensors.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a “first inventor to file” system in which, assuming that other requirements of patentability are met, the first inventor to file a patent application will be entitled to the patent regardless of whether a third-party was first to invent the claimed invention. A third-party that files a patent application in the USPTO after March 2013 but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third-party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we may not be certain that we or our licensors are the first to either (1) file any patent application related to our product candidates or (2) invent any of the inventions claimed in the patents or patent applications.

The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and/or those of our licensors and the enforcement or defense of our issued patents or those of our licensors, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Changes in U.S. patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect OJEMDA and our product candidates.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves a high degree of technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced with respect to our patents or third-party patents. In addition, the U.S. Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us.

For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. The Federal Circuit recently issued the In Re: Cellect, LLC decision that involves the interaction of patent term adjustment, or PTA, terminal disclaimers, and obviousness-type double patenting. This decision creates uncertainty to the patent terms of certain U.S. patents that share the same priority claim where one expires later than another due to accrued PTA. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patent and the patents we might obtain or license in the future.

Additionally, starting from June 1, 2023, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court, or the UPC. This will be a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC may be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of the new unitary patent system.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We and/or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. In addition, we cannot assure you that all inventors have been or will be identified by us and/or by our collaborators despite diligent effort. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Our licensors may have relied on third-party consultants or collaborators such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our in-licensed patents, they may be able to

license such patents to our competitors, and our competitors could market competing products. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations and prospects.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain patent term extension for our product and product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing authorization of our product and product candidates, one or more of our U.S. patents or those of our licensors may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. A maximum of one patent may be extended per FDA approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon marketing authorization of our product candidates. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and may launch their product earlier than might otherwise be the case.

We may not be able to protect our intellectual property rights throughout the world.

Although we have pending patent applications in the United States and other countries, filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our patents, the patents of our licensors or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or our licensors' patents or marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents or the patents of our licensors at risk of being invalidated or interpreted narrowly and our patent applications or the patent applications of our licensors at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our

intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by regulations and governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents and/or applications and those of our licensors. We have systems in place to remind us to pay these fees, and we rely on our outside patent annuity service to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on our business.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We intend to use registered or unregistered trademarks or trade names to brand and market ourselves and our products. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

We rely in part on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced, and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

We may be subject to claims that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets.

We have entered into or may enter in the future into non-disclosure and confidentiality agreements to protect the proprietary positions of third parties, such as outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors, potential partners and

other third parties. We may become subject to litigation where a third party asserts that we or our employees inadvertently or otherwise breached the agreements and used or disclosed trade secrets or other information proprietary to the third parties. Defense of such matters, regardless of their merit, could involve substantial litigation expense and be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions. Moreover, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise successfully commercializing OJEMDA and our product candidates and technology. Failure to defend against any such claim could subject us to significant liability for monetary damages or prevent or delay our developmental and commercialization efforts, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

Parties making claims against us may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, operating results, financial condition and prospects.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is common in the biopharmaceutical industry, in addition to our employees, we engage the services of consultants to assist us in the development of OJEMDA and our product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other pharmaceutical companies including our competitors or potential competitors. We may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

The patent protection and patent prosecution for OJEMDA and some of our product candidates may be dependent on third parties.

While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to OJEMDA and our product candidates, there may be times when the filing and prosecution activities for patents and patent applications relating to OJEMDA and our product candidates are controlled by our licensors or collaboration partners. If any of our licensors or collaboration partners fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering OJEMDA and our product candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize OJEMDA and those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

Currently, our intellectual property protection includes patents and patent applications that we have in-licensed from, among others, Viracta Therapeutics, Inc., Takeda Pharmaceutical Company Limited, Merck KGaA, Darmstadt, Germany and MabCare. Our exclusive and non-exclusive licenses may be subject to certain retained rights, which may adversely impact our competitive position. We do not control the prosecution and maintenance of several of the licensed patent portfolios; thus, we cannot assure you that the licensed patent families will be prepared, filed, prosecuted, or maintained in a manner consistent with the best interests of our business. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Significant Agreements.” Our licensed patent portfolio may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing products similar to OJEMDA and our product candidates.

Intellectual property discovered through government funded programs may be subject to federal regulations such as “march-in” rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.

Some of our own issued patents or pending patent applications may have been generated through the use of U.S. government funding, and we may acquire or license in the future intellectual property rights that have been generated through the use of U.S. government funding or grants. Pursuant to the Bayh-Dole Act of 1980, the U.S. government has certain rights in inventions developed with government funding. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to

require us to grant exclusive, partially exclusive or non-exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). If the U.S. government exercised its march-in rights in our existing or future intellectual property rights that are generated through the use of U.S. government funding or grants, we could be forced to license or sublicense intellectual property developed by us or that we license on terms unfavorable to us, and there can be no assurance that we would receive compensation from the U.S. government for the exercise of such rights. The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property.

Geo-political actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors.

Certain geo-political actions in the United States or other countries may increase the uncertainties and costs related to the prosecution or maintenance of our patent applications, or those of our current or future licensors. For example, the United States and foreign government actions related to Russia's invasion of Ukraine may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees that have citizenship or nationality in, are registered in, or have predominately primary place of business or profit-making activities in the United States and other countries that Russia has deemed unfriendly without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia.

Risks Related to Our Common Stock

An active and liquid trading market for our common stock may never be sustained. As a result, you may not be able to resell your shares of common stock at or above the purchase price.

An active trading market for our common stock may never be sustained. The market value of our common stock may decrease from the purchase price. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the purchase price. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares.

Furthermore, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic collaborations or acquire companies or products by using our shares of common stock as consideration.

Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

• timing and variations in the level of expense related to the current or future development of our programs;

• timing and status of enrollment for our clinical trials;

• results of clinical trials, or the addition or termination of clinical trials or funding support by us or potential future partners;

• our execution of any collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under potential future arrangements or the termination or modification of any such potential future arrangements;

• any intellectual property infringement, misappropriation or violation lawsuit or opposition, interference or cancellation proceeding in which we may become involved;

• additions and departures of key personnel;

• strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;

• if a product candidate we develop receives marketing authorization, the timing and terms of such approval and market acceptance and demand for such product;

• the timing and cost to establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing authorization and intend to commercialize on our own or jointly with future collaborators;

• regulatory developments affecting current or future product candidates or products, if any, or those of our competitors;

• the amount of expense or gain associated with the change in value of the success payments and contingent consideration;

• changes in general market and economic conditions, such as due to rising interest rates, inflation, actual or perceived instability in the global banking system, uncertainty with respect to the federal debt ceiling and budget and potential government shutdowns related thereto, global regional conflicts and public health epidemics;

• business development activities, such as additional program in-licensing, which could result in up-front payments or increased development expenses; and

• cybersecurity incidents.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

The market price of our common stock is likely to be highly volatile, which could result in substantial losses for purchasers of our common stock.

The market price of our common stock is likely to continue to be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. As a result of this volatility, you may not be able to sell your shares of common stock at or above the price paid. The market price for our common stock may be influenced by many factors, including the other risks described in this “Risk Factors” section and the following:

• results of preclinical studies or clinical trials by us or those of our competitors or by existing or future collaborators or licensing partners;

• the timing and enrollment status of our clinical trials;

• changes in the development status of our product candidates, including variations in the level of expense related to the development of our programs or funding support by us or by existing or future collaborators or licensing partners;

• regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our business;

• the success of competitive products or technologies;

• introductions and announcements of new product candidates by us, our future collaboration partners, or our competitors, and the timing of these introductions or announcements;

• actions taken by regulatory agencies with respect to our product candidates, clinical studies, manufacturing process or sales and marketing terms;

• our execution of any collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under existing or future arrangements or the termination or modification of any such existing or future arrangements;

• actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us;

• the success of our efforts to acquire or in-license additional technologies or product candidates;

• announced or completed significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;

• developments or disputes concerning our intellectual property and proprietary rights;

• the recruitment or departure of key personnel;

• changes in the structure of healthcare payment systems;

• actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;

• our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;

• speculation in the press or investment community;

• share price and fluctuations of trading volume of our common stock;

• the impact of interest rate increases on the overall stock market and the market for biopharmaceutical company stocks;

• fluctuations in the valuation of companies perceived by investors to be comparable to us;

• sales of shares of our common stock by us, insiders or our stockholders;

• our ability or inability to raise additional capital and the terms on which we raise it;

• the concentrated ownership of our common stock;

• changes in accounting principles;

• natural disasters and other calamities;

• general economic, industry and market conditions, including inflation, actual or perceived instability in the global banking system and uncertainty with respect to the federal debt ceiling and budget and potential government shutdowns related thereto, many of which are beyond our control;

• other events or factors, including those resulting from global pandemics, such as the COVID-19 pandemic, or war, incidents of terrorism or responses to these events, including global regional conflicts; and

• cybersecurity incidents.

In addition, the stock market in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme price and volume fluctuations, including as a result of the COVID-19 pandemic, increase in inflation and changes in interest rates, as well as disruptions to the supply chain, that have been often unrelated or disproportionate to the operating performance of the issuer. Furthermore, the trading price of our common stock may be adversely affected by third parties trying to drive down the market price. Short sellers and others, some of whom post anonymously on social media, may be positioned to profit if our stock declines and their activities can negatively affect our stock price. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and adverse impact on the market price of our common stock.

In the past, securities class action litigation has often been brought against public companies following declines in the market price of their securities. This risk is especially relevant for biopharmaceutical companies, which have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and our resources, which could harm our business.

We do not currently intend to pay dividends on our common stock and, consequently, our stockholders' ability to achieve a return on their investment will depend on appreciation of the value of our common stock.

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings to support operations and to finance the growth and development of our business. We do not intend to declare or pay any cash dividends on our capital stock in the foreseeable future. As a result, any investment return on our common stock will depend upon increases in the value for our common stock, which is not certain.

A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly.

The holders of an aggregate of 87,692,916 shares of our outstanding common stock as of June 30, 2024 will have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements

that we may file for ourselves or our stockholders. We also have registered shares of common stock that we may issue under our equity incentive plans. These shares are freely tradeable in the public market upon issuance.

We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of our outstanding options or vesting of outstanding restricted stock unit awards, or the perception that such sales may occur, could adversely affect the market price of our common stock.

We also expect that significant additional capital may be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. To the extent that additional capital is raised through the sale and issuance of shares or other securities convertible into shares, our stockholders will be diluted. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Based on the beneficial ownership of our common stock as of June 30, 2024, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned 46.6% of our voting stock. The voting power of this group may increase to the extent they convert shares of non-voting common stock they hold into common stock. As a result, these stockholders, if acting together, will continue to have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, amendment of our organizational documents, any merger, consolidation or sale of all or substantially all of our assets and any other significant corporate transaction. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock.

Anti-takeover provisions in our charter documents and under Delaware law could prevent or delay an acquisition of us, which may be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Our restated certificate of incorporation and our amended and restated bylaws contain provisions that could delay or prevent a change in control of our company. These provisions could also make it difficult for stockholders to elect directors who are not nominated by current members of our board of directors or take other corporate actions, including effecting changes in our management. These provisions:

- establish a classified board of directors so that not all members of our board are elected at one time;
- permit only the board of directors to establish the number of directors and fill vacancies on the board;
- provide that directors may only be removed “for cause” and only with the approval of two-thirds of our stockholders;
- require super-majority voting to amend some provisions in our restated certificate of incorporation and restated bylaws;
- authorize the issuance of “blank check” preferred stock that our board could use to implement a stockholder rights plan;
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting; and
- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

In addition, Section 203 of the Delaware General Corporation Law, or DGCL, may discourage, delay or prevent a change in control of our company. Section 203 imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 15% or more of our common stock.

The exclusive forum provision in our organizational documents may limit a stockholder’s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers or other employees, or the underwriters of any offering giving rise to such claim, which may discourage lawsuits with respect to such claims.

Our restated certificate of incorporation provides that, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware is the exclusive forum for: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our restated certificate of incorporation or our amended and restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. This exclusive forum provision does not apply to suits brought to enforce a duty or liability created by the Securities Exchange Act of 1934, as amended, or the Exchange Act. It could apply, however, to a suit that falls within one or more of the categories enumerated in the exclusive forum provision.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, or the underwriters of any offering giving rise to such claims, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provisions contained in our restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations and financial condition.

Section 22 of the Securities Act of 1933, as amended, or the Securities Act, creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Our amended and restated bylaws provide that the federal district courts of the United States of America will, to the fullest extent permitted by law, be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or a Federal Forum Provision, including for all causes of action asserted against any defendant named in such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. Our decision to adopt a Federal Forum Provision followed a decision by the Supreme Court of the State of Delaware holding that such provisions are facially valid under Delaware law. While federal or state courts may not follow the holding of the Delaware Supreme Court or may determine that the Federal Forum Provision should be enforced in a particular case, application of the Federal Forum Provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court, and our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Section 27 of the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. In addition, neither the exclusive forum provision nor the Federal Forum Provision applies to suits brought to enforce any duty or liability created by the Exchange Act. Accordingly, actions by our stockholders to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder must be brought in federal court, and our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities shall be deemed to have notice of and consented to our exclusive forum provisions, including the Federal Forum Provision. These provisions may limit a stockholders' ability to bring a claim and may result in increased costs for a stockholder to bring such a claim, in a judicial forum of their choosing for disputes with us or our directors, officers, or other employees, or the underwriters of any offering giving rise to such claim, which may discourage lawsuits against us and our directors, officers, and other employees.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our company, our common stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. We do not have any control over the analysts, or the content and opinions included in their reports. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our preclinical studies and future clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of such analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause a decline in our stock price or trading volume.

General Risk Factors

We incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Select Market, or Nasdaq, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we

expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. The increased costs may require us to reduce costs in other areas of our business or increase the prices of our products once commercialized. Moreover, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

If we fail to maintain proper and effective internal controls over financial reporting our ability to produce accurate and timely financial statements could be impaired.

Pursuant to Section 404 of the Sarbanes-Oxley Act, our management is required to report upon the effectiveness of our internal control over financial reporting and our independent registered public accounting firm is required to attest to the effectiveness of our internal control over financial reporting in our annual reports on Form 10-K. The rules governing the standards that must be met for our management and our independent registered public accounting firm to assess our internal control over financial reporting are complex and require significant documentation, testing, and possible remediation. In connection with our and our independent registered public accounting firm's evaluations of our internal control over financial reporting, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. This process will be time-consuming, costly and complicated.

Any failure to maintain internal control over financial reporting, including any failure to implement required new or improved controls, or difficulties encountered in their implementation, could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we or our independent registered public accounting firm are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. In addition, we do not have a formal risk management program for identifying and addressing risks to our business in other areas.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock may be volatile. The stock market in general, and Nasdaq and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

Unfavorable global economic conditions could adversely affect our business, financial condition, stock price and results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, the global financial crisis of 2007-2008 caused extreme volatility and disruptions in the capital and credit markets. Similarly, the volatility associated with the COVID-19 pandemic caused significant instability and disruptions in the capital and credit markets and, in recent months, the global economy has been impacted by increasing interest rates and inflation, as well as the possibility of a recession or further economic downturn. Moreover, there have been concerns with respect to the stability of the global banking system. For example, on March 10, 2023, Silicon Valley Bank, or SVB, one of our banking partners, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or the FDIC, as receiver. While we only had a minimal amount of our cash directly at SVB and, since that date, the FDIC has stated that all depositors of SVB will be made whole, there is no guarantee that the federal government would guarantee all depositors as they did with SVB depositors in the event of further bank closures and continued instability in the global banking system may adversely impact our business and financial condition. Likewise, the capital and credit markets may be adversely affected by global regional conflicts, and the possibility of wider or additional global conflicts, global sanctions imposed in response thereto or an energy crisis. A severe or prolonged economic downturn, such as the global financial crisis, could result in a variety of risks to our business, including a decrease in the demand for our drug candidates and in our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy also could strain our suppliers, possibly resulting in supply disruption. We cannot anticipate all of the ways in which the foregoing, and the current economic climate and financial market conditions generally, could adversely impact our business. Furthermore, our stock price may decline due in part to the volatility of the stock market and any general economic downturn.

Further, our business and operations may be impacted by the political instability and military hostilities in multiple geographies including Ukraine, the Middle East and the tensions between China and Taiwan. We are closely monitoring the unfolding events of the armed conflict in Israel which began in October 2023. While this conflict is still evolving, to date, the conflict has not had an adverse impact on our business results of operations. However, if the conflict continues to worsen or intensify, any business interruptions or spillover effects could adversely affect our business and operations.

Item 2. Unregistered Sales of Equity Securities, Use of Proceeds and Issuer Purchases of Equity Securities.

Unregistered Sales of Equity Securities

None.

Use of Proceeds

None.

Issuer Purchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

The exhibits filed or furnished as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index below.

		Incorporated by Reference				
Exhibit Number	**Description**	**Form**	**File No.**	**Filing Date**	**Exhibit**	**Filed/Furnished Herewith**
10.1†^	Asset Purchase Agreement, dated May 29, 2024.					X
10.2†^	Exclusive License Agreement by and between MabCare Therapeutics and Day One Biopharmaceuticals, Inc. dated June 17, 2024.					X
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
101.INS	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document).					X
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents.					X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)					X

* This certification is deemed not filed for purposes of section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

† Registrant has omitted portions of the exhibit as permitted under Item 601(b)(10) of Regulation S-K.

^ Registrant has omitted schedules and exhibits pursuant to Item 601(a)(5) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of the omitted schedules and exhibits to the SEC upon request.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

DAY ONE BIOPHARMACEUTICALS, INC.

Date: August 2, 2024

By: /s/ Jeremy Bender, Ph.D., M.B.A.
Jeremy Bender, Ph.D., M.B.A.
Chief Executive Officer and President
Principal Executive Officer

Date: August 2, 2024

By: /s/ Charles N. York II, M.B.A.
Charles N. York II, M.B.A.
Chief Operating Officer and Chief Financial Officer
Principal Financial and Accounting Officer

Exhibit 10.1

Execution Version

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO DAY ONE BIOPHARMACEUTICALS IF PUBLICLY DISCLOSED.

ASSET PURCHASE AGREEMENT

BY AND BETWEEN

[*]

AND

DAY ONE BIOPHARMACEUTICALS, INC.

MAY 29, 2024

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List of Exhibits

ASSET PURCHASE AGREEMENT

This ASSET PURCHASE AGREEMENT (this "***Agreement***") is made and entered into as of May 29, 2024 (the "***Effective Date***") by and between **[*]** ("***Buyer***") and **DAY ONE BIOPHARMACEUTICALS, INC.**, a Delaware corporation ("***Seller***"). Buyer and Seller may hereinafter be referred to individually as a "***Party***" and collectively as the "***Parties***."

RECITALS

WHEREAS, Seller is the holder of all right, title and interest in and to the Priority Review Voucher (as defined below);

WHEREAS, Seller has agreed to pay a specified portion of the consideration it receives from the sale of the Priority Review Voucher to Viracta Therapeutics, Inc., a Delaware corporation ("***Viracta***"), pursuant to the Viracta License Agreement, dated December 16, 2019, by and between Buyer and Viracta, as amended by that certain amendment dated March 4, 2024 (the "***Viracta Agreement***");

WHEREAS, Seller and Buyer each (a) desire that Buyer purchase from Seller, and Seller sell, transfer and assign to Buyer, the Purchased Assets (as defined below), all on the terms set forth herein (such transaction, the "***Asset Purchase***") and (b) in furtherance thereof, have adopted and approved this Agreement and, upon the terms and subject to the conditions set forth in this Agreement, have adopted and approved the Asset Purchase as contemplated by this Agreement in accordance with all applicable Legal Requirements (as defined below); and

WHEREAS, Seller and Buyer desire to make certain representations, warranties, covenants, and other agreements as set forth herein in connection with the Asset Purchase contemplated by this Agreement.

NOW, THEREFORE, in consideration of the foregoing and their mutual undertakings hereinafter set forth, and for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties, intending to be legally bound, agree as follows:

ARTICLE 1
DEFINITIONS TC "ARTICLE 1 DEFINITIONS" \F C \L "1"

1.1 Certain Definitions. As used in this Agreement, the following capitalized terms shall have the meanings indicated below:

(a) "***Action***" means any claim, audit, examination, action, cause of action or suit (whether in contract or tort or otherwise), litigation (whether at law or in equity, whether civil or criminal), assessment, arbitration, mediation, investigation, hearing, charge, complaint, demand, notice, or proceeding.

(b) "***Affiliate***" means, with respect to any Party, any Person that, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with, such Party, for so long as such control exists, whether such Person is or becomes an

Affiliate on or after the Effective Date. A Person shall be deemed to "control" another Person if it: (i) owns, directly or indirectly, beneficially or legally, at least fifty percent (50%) of the outstanding capital stock, voting securities, or other ownership interest (or such lesser percentage which is the maximum allowed to be owned by such Person in a particular jurisdiction) of such other Person (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity) or (ii) has the power, whether pursuant to Contract, ownership of securities or otherwise, to direct the management and policies of such other Person.

(c) "***Agreement***" has the meaning set forth in the Preamble.

(d) "***Approval Letter***" means the NDA 217700 approval letter, dated April 23, 2024, from the FDA to Seller, reflecting the FDA Approval and the grant of the Priority Review Voucher attached hereto as Exhibit A.

(e) "***Asset Purchase***" has the meaning set forth in the Recitals.

(f) "***Business Day***" means a day (i) other than Saturday or Sunday and (ii) on which commercial banks are open for business in New York, New York, United States.

(g) "***Buyer***" has the meaning set forth in the Preamble.

(h) "***Confidential Information***" means (i) any and all confidential and proprietary information, including data, results, conclusions, know-how, experience, financial information, plans and forecasts, that may be delivered, made available, disclosed or communicated by a Party or its Affiliates or their respective Representatives to the other Party or its Affiliates or their respective Representatives, related to the subject matter hereof or otherwise in connection with this Agreement and (ii) the terms, conditions and existence of this Agreement. "*Confidential Information*" will not include information that (A) at the time of disclosure, is generally available to the public, (B) after disclosure hereunder, becomes generally available to the public, except as a result of a breach of this Agreement by the recipient of such information, (C) becomes available to the recipient of such information from a Third Party that is not legally or contractually prohibited by the disclosing Party from disclosing such Confidential Information; or (D) was developed by or for the recipient of such information without the use of or reference to any of the Confidential Information of the disclosing Party or its Affiliates, as evidenced by the recipient's contemporaneous written records. Notwithstanding anything herein to the contrary, all Confidential Information included within the Purchased Assets shall constitute Confidential Information of the Buyer from and after the Effective Date.

(i) "***Confidentiality Agreement***" means that certain confidentiality agreement by and between [*] and Seller, dated [*].

(j) "***Consent***" means any and all filings, authorizations, consents, approvals, notices, permits, orders, registrations, or declarations.

(k) "***Contract***" means any written or oral legally binding contract, agreement, instrument, commitment, or undertaking (including leases, licenses, mortgages, notes, guarantees, sublicenses, subcontracts, and purchase orders).

(l) "***Effective Date***" has the meaning set forth in the Preamble.

(m) "***Encumbrance***" means any lien, pledge, charge, mortgage, owner's mortgage, easement, encroachment, imperfection of title, title exception, title defect, right of possession, right of negotiation or refusal, leasehold interest, security interest, encumbrance, adverse claim, interference, or other restriction on transfer, ownership, or use.

(n) "***FDA***" means the U.S. Food and Drug Administration.

(o) "***FDA Approval***" means the marketing authorization for Ojemda (tovorafenib) Tablet issued by the FDA to Seller effective on April 23, 2024, relating to NDA 217700, which was submitted under Section 505(b) of the FFDCA.

(p) "***FFDCA***" means the United States Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended from time to time, together with any rules, regulations, and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

(q) "***Fundamental Breach Event***" has the meaning set forth in Section 6.7.

(r) "***Fundamental Representations***" means the representations and warranties contained in Section 3.1 (Organization; Standing and Power), Section 3.2 (Due Authority), Section 3.3 (No Contravention), Section 3.5 (Title to Purchased Assets), Section 3.6 (Compliance with Legal Requirements), Section 3.9 (Revocation; Use of Purchased Assets), Section 3.10 (Marketed Product), Section 3.11 (Brokers), Section 3.12 (Taxes), Section 4.1(Organization; Standing and Power), Section 4.2 (Authority), Section 4.3 (No Contravention), and Section 4.5 (Brokers).

(s) "***Governmental Entity***" means any supranational, national, state, municipal, local or foreign government, any court, tribunal, arbitrator, administrative agency, commission, or other governmental official, authority, or instrumentality, in each case, whether domestic or foreign, any stock exchange or similar self-regulatory organization, or any quasi-governmental, private body or arbitral body exercising any executive, legislative, judicial, quasi-judicial, regulatory, taxing, importing, administrative, or other governmental or quasi-governmental authority.

(t) "***Indemnified Party***" means any of the Buyer Indemnified Parties or Seller Indemnified Parties, as applicable.

(u) "***Indemnifying Party***" means any Person against whom a claim for indemnification is being asserted under any provision of ARTICLE 6.

(v) "***Indirect Taxes***" has the meaning set forth in Section 2.8.

(w) "***Judgment***" means any orders, writs, injunctions, awards, judgments, settlements, stipulations, determinations, and decrees entered by or with any Governmental Entity.

(x) "***Knowledge***" means[*].

(y) "***Law***" means any federal, state, foreign, local, municipal, or other law, statute, constitution, principle of common law, resolution, ordinance, code, edict, decree, rule, regulation, ruling or requirement issued, enacted, adopted, promulgated, implemented, or otherwise put into effect by or under the authority of any Governmental Entity.

(z) "***Legal Requirement***" means any federal, state, foreign, local, municipal or other law, statute, constitution, principle of common law, resolution, ordinance, code, rule, regulation, ruling or requirement issued, enacted, adopted, promulgated, implemented or otherwise put into effect by or under the authority of any Governmental Entity and any Orders applicable to a Party or to any of its assets, properties or businesses. Legal Requirements shall include, with respect to Seller or its Affiliates, any responsibilities, requirements, parameters and conditions relating to the Priority Review Voucher set forth in (i) the Approval Letter, (ii) any other correspondence received by Seller or its Affiliates from the FDA regarding the Priority Review Voucher, (iii) Section 529 of the FFCA (21 U.S.C. § 360ff), or (iv) in the FDA's Draft Guidance, "Rare Pediatric Disease Priority Review Vouchers —Guidance for Industry" (July 2019).

(aa) "***Liabilities***" means all debts, liabilities, and obligations, whether presently in existence or arising hereafter, accrued or fixed, absolute or contingent, matured or unmatured, determined or determinable, asserted or unasserted, known or unknown, including those arising under any Law, Action, or Judgment and those arising under any Contract.

(bb) "***Losses***" means all losses, Liabilities, damages, claims, causes of action, Judgments, awards, suits, Taxes, fines, penalties, costs, or expenses (including reasonable attorneys' and experts' fees and expenses).

(cc) "***Market,***" "***Marketed***" or "***Marketing***" means to market a drug as described in Section 529(e)(1) of the FFDCA.

(dd) [*]

(ee) [*]

(ff) "***Person***" means any natural person, company, corporation, limited liability company, general partnership, limited partnership, trust, proprietorship, joint venture, business organization, or Governmental Entity.

(gg) "***PHSA***" means the United States Public Health Service Act, 42 U.S.C. § 201 et seq., as amended from time to time, together with any rules, regulations, and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

(hh) "***Priority Review***" has the meaning given in Section 529(a)(1) of the FFDCA.

(ii) "***Priority Review Voucher***" means the priority review voucher issued by the Secretary of the Department of Health and Human Services pursuant to Section 529(b)(1) of the FFDCA to Seller and assigned tracking number PRV NDA 217700 that entitles the holder of such voucher to Priority Review of a single human drug application submitted under Section 505(b)(1) of the FFDCA or section 351(a) of the PHSA.

(jj) "***Purchased Assets***" means (i) the Priority Review Voucher and (ii) any and all rights, benefits and entitlements with respect thereto afforded to the holder of such Priority Review Voucher.

(kk) "***Rare Pediatric Disease***" means rare pediatric disease as defined in Section 529(a)(3) of the FFDCA.

(ll) "***Representative***" means, with respect to a particular Person, any director, officer, manager, employee, agent, consultant, advisor, accountant, financial advisor, legal counsel, or other representative of that Person.

(mm) "***SEC***" has the meeting set forth in Section 5.3.

(nn) "***Tax***" or "***Taxes***" means any net income, alternative or add-on minimum tax, gross income, gross receipts, sales, use, value added tax, ad valorem, transfer, franchise, profits, license, withholding, payroll, employment, excise, severance, stamp, occupation, municipal tax, municipal surcharge premium, property, environmental or windfall profit tax, social security contribution, or other tax of any kind whatsoever, together with any interest or any penalty, addition to tax or additional amount in the nature of a tax, whether disputed or not, including (i) the tax liability of any other Person imposed pursuant to Treasury Regulations Section 1.1502-6 or any similar provision of other tax Law and (ii) the obligation to indemnify or assume or otherwise succeed to the tax liability of any other Person, by Contract or pursuant to any Law.

(oo) "***Third Party***" means any Person other than a Party and such Party's Affiliates.

(pp) "***Transfer Taxes***" has the meaning set forth in Section 2.7.

(qq) "***Unstated Indirect Taxes***" has the meaning set forth in Section 2.8.

(rr) "***U.S.***" means United States of America.

(ss) "***Viracta***" has the meaning set forth in the Recitals.

(tt) "***Viracta Agreement***" has the meaning set forth in the Recitals.

(uu) "***Viracta Payment and Release Letter***" means that certain Payment and Release Letter duly executed between Seller and Viracta, attached hereto as Exhibit B.

Other capitalized terms defined elsewhere in this Agreement and not defined in this Section 1.1 shall have the meanings assigned to such terms in this Agreement.

ARTICLE 2
PURCHASE AND SALE TC "ARTICLE 2 PURCHASE AND SALE" \F C \L "1"

2.1 Purchase and Sale of Purchased Assets.

(a) Upon the terms and subject to the conditions of this Agreement, Buyer hereby irrevocably purchases from Seller and Seller, on behalf of itself and its Affiliates, hereby irrevocably sells, transfers, conveys, assigns, and delivers to Buyer all of Seller's and its Affiliates' rights, title, and interests in and to the Purchased Assets free and clear of all Encumbrances. Seller shall perform all actions necessary to facilitate the transfer of the Purchased Assets to Buyer.

(b) Notwithstanding anything in this Agreement to the contrary, neither Buyer nor any of its Affiliates shall assume, nor shall Buyer or any of its Affiliates be liable for, or otherwise be obligated to pay, perform, or discharge, any Liabilities of Seller or its Affiliates, including any Liabilities arising from or related to Seller's ownership prior to the Effective Date of any rights with respect to the Purchased Assets (other than obligations that are imposed by applicable Legal Requirements solely on the holder of the Priority Review Voucher in respect of its use or transfer following the sale thereof pursuant to this Agreement) (such Liabilities, the "***Excluded Liabilities***").

2.2 Purchase Price. The total consideration to be paid by Buyer to Seller and Viracta in accordance with Section 2.5 for all of the Purchased Assets shall be ONE HUNDRED AND EIGHT MILLION U.S. DOLLARS (U.S. $108,000,000.00) (the "***Purchase Price***").

2.3 Title Passage; Delivery of Purchased Assets.

(a) *Title Passage*. Upon the execution of this Agreement and consummation of the transactions herein contemplated, including execution and delivery of the Bill of Sale, all of the rights, title, and interests in and to the Purchased Assets shall pass to Buyer free and clear of all Encumbrances.

(b) *Method of Delivery of Assets*. Within [*] following the Effective Date, Seller shall submit, or cause to be submitted, to the FDA the separate notifications referred to in Section 2.4(b) and Section 2.5(d), respectively, as a submission to NDA 217700 through the FDA's Electronic Submissions Gateway under the cover letter in the form attached as Exhibit 2.3(b). Seller shall provide to Buyer, within [*] following their submission to the FDA, confirmation from the FDA of successful submission and a complete copy of such submission.

(c) *Filings; Notifications*. Buyer and Seller agree to cooperate and assist each other with respect to all filings and notifications to the FDA related to the transfer and assignment of the Purchased Assets.

2.4 Deliveries by Seller. Upon the execution of this Agreement, Seller shall deliver, or cause to be delivered, to Buyer the following:

(a) a duly executed counterpart of the Bill of Sale substantially in the form attached hereto as Exhibit 2.4(a);

(b) a copy of the notification of the purchase and sale of the Priority Review Voucher pursuant to this Agreement to be submitted to the FDA by, or on behalf of, Seller pursuant to Section 2.3(b), which notification shall be in the form of Exhibit 2.4(b) or such other form as the FDA may require as of the Effective Date;

(c) a properly completed, validly executed, true and correct Internal Revenue Service Form W-9 certifying that Seller is not subject to backup withholding for United States federal income tax purposes; and

(d) a properly completed, validly executed, true and correct Internal Revenue Service Form W-9 certifying that Viracta is not subject to backup withholding for United States federal income tax purposes.

2.5 Deliveries by Buyer. Upon the execution of this Agreement, Buyer shall deliver, or cause to be delivered, to Seller the following:

(a) to Seller an amount equal to NINETY NINE MILLION AND NINE HUNDRED THOUSAND U.S. Dollars (U.S. $99,900,000), by wire transfer of immediately available funds, to the following Seller account:

Seller Bank Name: [*]
Seller Bank Address: [*]
Seller ABA: [*]
Seller Account Number: [*]
Seller Account Name: [*]

(b) (ii) on behalf of Seller, to Viracta an amount equal to EIGHT MILLION AND ONE HUNDRED THOUSAND U.S. Dollars (U.S. $8,100,000), by wire transfer of immediately available funds, to the following account:

Viracta Bank Name: [*]
Viracta Bank Address: [*]
Viracta ABA: [*]
Viracta Account Number: [*]

in full satisfaction of its obligation to pay the Purchase Price to Seller, and fulfill Seller's obligation under Section 6.2.1 (Development Milestone Payments) of the Viracta Agreement;

(c) a duly executed counterpart of the Bill of Sale substantially in the form attached hereto as Exhibit 2.4(a); and

(d) a copy of the notification of the purchase and sale of the Priority Review Voucher pursuant to this Agreement to be submitted to the FDA by, or on behalf of, Seller pursuant to Section 2.3(b), which notification shall be in the form of Exhibit 2.5(d) or such other form as the FDA may require as of the Effective Date.

2.6 [*].

2.7 [*].

2.8 [*].

2.9 [*].

2.10 [*].

ARTICLE 3
REPRESENTATIONS AND WARRANTIES OF SELLER TC "ARTICLE 3 REPRESENTATIONS AND WARRANTIES OF SELLER" \F C \L "1"

Seller hereby represents and warrants to Buyer, as of the Effective Date (or in the case of representations and warranties that are made as of a specified date, as of such specified date) as follows:

3.1 Organization, Standing, and Power. Seller is a corporation duly organized, validly existing, and in good standing under the laws of Delaware. Seller has the requisite corporate power and authority to own, operate, and lease its properties and to carry on its business as presently conducted and is duly qualified or licensed to do business and is in good standing in each jurisdiction where the character of its properties owned or leased or the nature of its activities make such qualification or licensing necessary, except where the failure to be so qualified or licensed would not, individually or in the aggregate, reasonably be expected to adversely affect any of the Purchased Assets, Seller's ability to consummate the transactions contemplated by this Agreement, or Buyer's ownership and rights with respect to any of the Purchased Assets after the Effective Date. Seller is not in violation of its organizational documents, as amended to date.

3.2 Due Authority. Seller has all requisite corporate power and authority to execute and deliver, perform its obligations under, and consummate the transactions contemplated by this Agreement. The execution, delivery, and performance of this Agreement, and the consummation of the Asset Purchase, have been duly and validly authorized by all necessary corporate action on the part of Seller. This Agreement has been duly executed and delivered by Seller. This Agreement, upon due execution and delivery by the Parties, will constitute a valid and binding obligation of Seller enforceable against Seller in accordance with its terms, subject only to the effect, if any, of (a) applicable bankruptcy and other similar Laws affecting the rights of creditors generally and (b) rules of Law governing specific performance, injunctive relief, and other equitable remedies (whether considered in an action at Law or in equity).

3.3 No Contravention. The execution and delivery by Seller of this Agreement does not, and the consummation of the transactions contemplated hereby, including the transfer of title to, ownership in, and possession of the Purchased Assets, will not (a) result in the creation of any Encumbrance on the Purchased Assets or (b) conflict with, or result in any violation of or default under (with or without notice or lapse of time, or both), or give rise to a right of termination, revocation, suspension, cancellation, or acceleration of any obligation or loss of any benefit under, or (except for the letters referenced in Section 2.3(b)) require any consent, approval, or waiver from any Person pursuant to, (i) any provision of the organizational or governing documents of Seller, in each case as amended to date, (ii) the Priority Review Voucher, the Approval Letter or any Contract to which Seller or any Affiliate of Seller is a party or bound which involves or affects in any way any of the Purchased Assets, or (iii) any Legal Requirements applicable to Seller or any Affiliate of Seller or any of the Purchased Assets.

3.4 No Consents. Except for the letters referenced in Section 2.3(b), no Consent of a Governmental Entity or any other Person is necessary or required in connection with the execution, delivery and performance by Seller of this Agreement, and the consummation by Seller or its Affiliates of the transactions contemplated hereby.

3.5 Title to Purchased Assets. Seller is the sole and exclusive owner of all rights, title, and interests in and to the Purchased Assets and owns good and transferable title to the Purchased Assets free and clear of any Encumbrances. Seller has performed all actions necessary to perfect its ownership of, and its ability to transfer, the Purchased Assets. Neither Seller nor any of its Affiliates has sold, transferred, conveyed, assigned, or delivered any Purchased Assets, or offered to do so, to any Person, and Seller has the full and sole right to sell, transfer, convey, assign, and deliver the Purchased Assets to Buyer free and clear of all Encumbrances.

3.6 Compliance with Legal Requirements. Seller and its Affiliates are, and at all times have been, in compliance with all Legal Requirements that are or were applicable to (a) Seller's and its Affiliates' conduct, acts, or omissions with respect to any of the Purchased Assets or (b) any of the Purchased Assets. None of Seller or any of its Affiliates has received any notice or other communication from any Person regarding any actual or alleged, possible, or potential violation of, or failure to comply with, any such Legal Requirement. Since the three (3) year period prior to the Effective Date and as it relates to the FDA Approval, the Approval Letter, the Priority Review Voucher or the activities giving rise to such FDA Approval, the Approval Letter or the Priority Review Voucher, neither Seller, nor any Affiliate of Seller, nor to the Knowledge of Seller, any representative of Seller or any Affiliate of Seller, has made an untrue statement of material fact or a fraudulent statement to the FDA or any other Governmental Entity, failed to disclose a material fact or a fraudulent statement to the FDA or any other Governmental Entity or committed an act, made a statement or failed to make a statement that, at the time such disclosure was made, would reasonably be expected to provide a basis for the FDA to revoke the Priority Review Voucher or invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities," set forth in 56 Fed. Reg. 46191 (September 10, 1991) or for any other Governmental Entity to invoke any similar policy.

3.7 Legal Proceedings. There is no pending or threatened Action involving Seller or any of its Affiliates, nor has there been any Action involving Seller or any of its Affiliates, and

neither Seller nor any of its Affiliates are a party or subject to the provisions of any Judgment, in each case, (a) that involves or affects (or may involve or affect) the issuance of, continued validity of, ownership of, transfer or license of, title to, or use of any of the Purchased Assets, including any such Action or Judgment that seeks to prohibit or limit in any respect, or place any conditions on, the ownership or use by Buyer or its Affiliates of any of the Purchased Assets, in each case, as a result of the transactions contemplated by this Agreement, or (b) that otherwise challenges or seeks to restrain, prohibit, prevent, enjoin, alter, or delay the consummation of the transactions contemplated by this Agreement.

3.8 Governmental Authorizations. Neither Seller nor any of its Affiliates is required to hold any license, registration, or permit issued by any Governmental Entity to own, use, or transfer the Purchased Assets, other than such licenses, registrations, or permits that have already been obtained.

3.9 Revocation; Use of Purchased Assets. The Priority Review Voucher has been duly granted and issued and has not been revoked, and there are no facts or circumstances [*] or result in the redemption or transfer of the Priority Review Voucher (other than pursuant to the transactions contemplated by this Agreement), or that would reasonably be expected to preclude or interfere with the sale and transfer of the Purchased Assets to Buyer or Buyer's use of the Purchased Assets following the Effective Date to obtain Priority Review or any other benefits associated with the Purchased Assets. Except for this Agreement, there is no Contract to which Seller or any Affiliate of Seller is a party that involves or affects the ownership of, licensing of, title to, sale or other transfer of, or use of any of the Purchased Assets. There is no term or condition imposed by the FDA as of the date hereof on the Priority Review Voucher that is not set forth in the Approval Letter or provided for under applicable Law. Seller has provided to Buyer true and complete copies of the Approval Letter and all other material written correspondence between Seller or any of its Affiliates and the FDA regarding the Priority Review Voucher, in each case, (a) with such redactions to any portion of the Approval Letter and such other material written correspondence that is not relevant to the Priority Review Voucher and (b) including any and all corrections with respect thereto. Neither Seller nor any of its Affiliates has notified the FDA, or permitted any Third Party to notify the FDA, of intent to use the Priority Review Voucher.

3.10 [*].

3.11 [*].

3.12 [*].

ARTICLE 4
REPRESENTATIONS AND WARRANTIES OF BUYER TC "ARTICLE 4 REPRESENTATIONS AND WARRANTIES OF BUYER" \F C \L "1"

Buyer hereby represents and warrants to Seller as of the Effective Date as follows:

4.1 Organization, Standing, and Power. Buyer is a limited liability company duly organized, validly existing, and in good standing under the laws of Delaware. Buyer has the

requisite power and authority to own, operate, and lease its properties and to carry on its business as presently conducted and is duly qualified or licensed to do business and is in good standing in each jurisdiction where the character of its properties owned or leased or the nature of its activities make such qualification or licensing necessary, except where the failure to be so qualified or licensed would not, individually or in the aggregate, reasonably be expected to adversely affect Buyer's ability to consummate the transactions contemplated by this Agreement.

4.2 Authority. Buyer has all requisite power and authority to execute and deliver, perform its obligations under, and consummate the transactions contemplated by, this Agreement. The execution, delivery, and performance of, and the consummation of the transactions contemplated by, this Agreement have been duly and validly approved and authorized by all necessary action on the part of Buyer. This Agreement has been duly executed and delivered by Buyer. This Agreement, upon due execution and delivery by the Parties, will constitute a valid and binding obligation of Buyer, enforceable against Buyer in accordance with its terms, subject only to the effect, if any, of (a) applicable bankruptcy and other similar Laws affecting the rights of creditors generally and (b) rules of Law governing specific performance, injunctive relief and other equitable remedies (whether considered in an action at Law or in equity).

4.3 No Contravention. The execution and delivery by Buyer of this Agreement does not, and the consummation of the transactions contemplated hereby will not, conflict with, or result in any violation of or default under (with or without notice or lapse of time, or both), or give rise to a right of termination, cancellation, or acceleration of any obligation or loss of any benefit under, (except for the letters referenced in Section 2.3(b)) or require any consent, approval, or waiver from any Person pursuant to, (a) any provision of the organizational or governing documents of Buyer, in each case as amended to date, (b) any Contract to which Buyer or any Affiliate of Buyer is a party or bound by or by which it or its assets or properties are bound or under which Buyer or any Affiliate of Buyer has material rights or benefits, or (c) any Legal Requirements applicable to Buyer.

4.4 No Consents. Except for the letters referenced in Section 2.3(b), no Consent of any Governmental Entity or any other Person is necessary or required in connection with the execution, delivery and performance by Buyer of this Agreement or the consummation by Buyer of the transactions contemplated hereby.

4.5 [*].

4.6 [*].

ARTICLE 5
COVENANTS TC "ARTICLE 5 COVENANTS" \F C \L "1"

5.1 Expenses. Whether or not the purchase and sale of the Purchased Assets and the other transactions contemplated by this Agreement are consummated, and except as otherwise set forth in this Agreement, each of the Parties shall bear its own fees and expenses incurred or owed in connection with the purchase and sale of the Purchased Assets, this Agreement, and the transactions contemplated hereby.

5.2 [*].

5.3 Public Announcements. Notwithstanding anything in this Agreement to the contrary, except as may be required by applicable Law or as may be required to comply with the requirements of any applicable stock exchange or any Governmental Entity, including the U.S. Securities and Exchange Commission (the "***SEC*")**, neither Party shall (a) disclose the existence or terms of this Agreement (other than disclosures to Representatives on a need-to-know basis and who are bound by confidentiality terms substantially no less stringent than the terms of this Agreement) or (b) issue any press release, publication, or other public announcement relating to this Agreement, the performance of this Agreement, or that otherwise identifies the other Party as a party to this Agreement, in each case, without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed. To the extent practicable, the disclosing Party shall give at least two (2) Business Days' advance notice of any legally required disclosure to the non-disclosing Party, and the non-disclosing Party may provide any comments on the proposed legally required disclosure during the foregoing time period; *provided* that such disclosing Party shall be under no obligation to accept any such comments provided by the non-disclosing Party but shall consider all such comments in good faith. The Parties acknowledge that Seller may be obligated to file a copy of this Agreement with the SEC. Without limiting the foregoing, Seller shall provide Buyer with a reasonable opportunity to review the proposed filing and, if requested by Buyer, Seller shall request, and use reasonable efforts to obtain, confidential treatment of this Agreement pursuant to applicable rules under the Securities Exchange Act of 1934, as amended, and the Freedom of Information Act and the rules promulgated thereunder to permit the filing of a redacted exhibit; *provided* that Buyer acknowledges that there is no assurance that such redactions will be permitted by the SEC and the SEC may require filing of the Agreement in full.

5.4 Use of Name. Except as expressly provided herein, neither Party shall mention or otherwise use the name, logo, or trademark of the other Party or any of its Affiliates (or any abbreviation or adaptation thereof) in any publication, press release, marketing, and promotional material, or other form of publicity or filing that is publicly available without the prior written approval of such other Party in each instance. The restrictions imposed by this Section 5.4 shall not prohibit either Party from making any disclosure identifying the other Party that, in the opinion of the disclosing Party's counsel, is required by applicable Law or the rules of a stock exchange on which the securities of the disclosing Party are listed; *provided* that such disclosing Party shall submit the proposed disclosure identifying the other Party in writing to the other Party as far in advance as reasonably practicable (and in no event less than two (2) Business Days prior to the anticipated date of disclosure) so as to provide a reasonable opportunity to comment thereon.

5.5 Compliance with Legal Requirements. Seller shall, and shall cause its Affiliates and each of their respective successors in interest and assigns to the Rare Pediatric Disease product for which the Priority Review Voucher was awarded to, comply in all material respects at all times with all Legal Requirements applicable to such Persons (as the sponsor of such Rare Pediatric Disease product and the initial recipient and owner of the Priority Review Voucher, as applicable), in any case relating to the Purchased Assets, and comply with any and all Legal Requirements applicable to such Persons that would impact the validity, maintenance, use, or transfer of the

Priority Review Voucher, or that would reasonably be expected to result in the revocation of the Priority Review Voucher if such Legal Requirements were not complied with. Seller shall promptly forward to Buyer any communications or notices it or its Affiliates receive from any Governmental Entity to the extent relating directly or indirectly to or otherwise materially impacting the Purchased Assets; *provided*, that Seller may redact any portion of such written communications or other notices that is not relevant to the Priority Review Voucher.

5.6 [*].

5.7 Confidentiality.

(a) With respect to Confidential Information received by any Party, such Party shall (i) keep such Confidential Information confidential, (ii) not use such Confidential Information for any reason other than to carry out the intent and purpose of this Agreement, and (iii) not disclose such Confidential Information to any Person, except in each case, as otherwise expressly permitted by this Agreement or with the prior written consent of the disclosing Party.

(b) A Party may disclose Confidential Information only to its Representatives on a need-to-know basis and shall (i) enforce the terms of this Section 5.7 as to its Representatives [*], (ii) take such action to the extent necessary to cause its Representatives [*] to comply with the terms and conditions of this Section 5.7 and (iii) be responsible and liable for any breach of this Section 5.7 by it or its Representatives [*].

(c) If a Party becomes compelled by a court or is requested by a Governmental Entity to make any disclosure that is prohibited or otherwise constrained by this Section 5.7, such Party shall provide the disclosing Party with prompt written notice of such compulsion or request so that it may seek an appropriate protective order or other appropriate remedy or waive compliance with the provisions of this Section 5.7. In the absence of a protective order or other remedy, the Party subject to the requirement to disclose may disclose that portion (and only that portion) of the Confidential Information that, based upon advice of its counsel, it is legally compelled to disclose or that has been requested by such Governmental Entity; *provided, however*, that such Party shall use reasonable efforts to obtain reliable assurance that confidential treatment will be accorded by any Person to whom any Confidential Information is so disclosed. For the avoidance of doubt, this Section 5.7(c) does not apply to those disclosures concerning this Agreement to which Section 5.3 applies.

(d) Nothing herein shall prohibit or otherwise restrict the disclosure of any Confidential Information by or on behalf of Buyer or its Affiliates to the FDA or other Governmental Entity to the extent required by the FDA or such other Governmental Entity to enable the use or transfer of the Priority Review Voucher; provided, that Buyer, its Affiliates and their respective Representatives shall use commercially reasonable efforts to obtain confidential treatment for any such disclosures.

5.8 Disclosure Concerning Use of the Priority Review Voucher. In the event that Buyer or any of its Affiliates uses (or notifies the FDA of its intent to use) the Priority Review Voucher in connection with a human drug application, Buyer or such Affiliate may, in any press release,

public announcement or other disclosure relating to its filing (or proposed filing) of the relevant human drug application, disclose that the Priority Review Voucher acquired from Seller has been used (or is intended to be used) in connection with such human drug application.

ARTICLE 6
INDEMNIFICATION AND LIMITATIONS OF LIABILITY TC "ARTICLE 6 INDEMNIFICATION AND LIMITATIONS OF LIABILITY" \F C \L "1"

6.1 Indemnification.

(a) Indemnification by Seller. Seller shall indemnify, defend and hold harmless Buyer and its Affiliates and its and their respective directors, officers, employees, partners, members, agents, Representatives, successors, and assigns (each, a "***Buyer Indemnified Party***") for, from and against any and all Losses, whether or not arising from, relating to, or otherwise in connection with a claim of a Third Party (each, a "***Third Party Claim***"), which any Buyer Indemnified Party may suffer, incur, sustain, or become subject to, to the extent arising from, relating to or otherwise in connection with (i) any breach of or inaccuracy in any representations and warranties of Seller made under this Agreement or any certificate or document delivered hereunder; (ii) any breach of or failure to perform any covenants or obligations of Seller made under this Agreement or any certificate or document delivered hereunder; (iii) Seller's grossly negligent acts, omissions or misrepresentations or wilful misconduct, in each case, in connection with this Agreement; and (iv) any and all Excluded Liabilities.

(b) Indemnification by Buyer. Buyer shall indemnify, defend and hold harmless Seller and its Affiliates, and its and their respective directors, officers, employees, agents, Representatives, successors, and assigns (each, a "***Seller Indemnified Party***") from and against any and all Losses, whether or not arising from, relating to or otherwise in connection with a Third Party Claim, which any Seller Indemnified Party may suffer, incur, sustain, or become subject to, to the extent arising from, relating to or otherwise in connection with (i) any breach of or inaccuracy in any representations and warranties of Buyer made under this Agreement or any certificate or document delivered hereunder; (ii) any breach of or failure to perform any covenants or obligations of Buyer made under this Agreement or any certificate or document delivered hereunder; and (iii) Buyer's grossly negligent acts, omissions or misrepresentations or willful misconduct, in each case, in connection with this Agreement.

6.2 Notice of Loss; Third Party Claims.

(a) A claim for indemnification for any matter not involving a Third Party Claim may be asserted by written notice to the Indemnifying Party. Such notice shall include the facts constituting the basis for such claim for indemnification, the Sections of this Agreement upon which such claim for indemnification is then based and an estimate, if possible, of the amount of Losses suffered or reasonably expected to be suffered by the Indemnified Party; *provided* that the failure to give such notification or any deficiency in such notification will not relieve such Indemnifying Party from any obligation under this ARTICLE 6, except (i) to the extent such failure to give such notification or such deficiency in such notification actually and materially prejudices

such Indemnifying Party or (ii) as provided in Section 6.3. If the Indemnifying Party does not notify the Indemnified Party within twenty (20) Business Days following its receipt of such notice that the Indemnifying Party affirmatively accepts liability in the specified amount for the indemnity claimed by the Indemnified Party under Section 6.1(a) or Section 6.1(b), as applicable, such indemnity claim specified by the Indemnified Party in such notice shall be deemed not accepted by the Indemnifying Party, in which case, the Indemnified Party may pursue its right to indemnification with respect to such indemnity claim under this ARTICLE 6 in accordance with the terms hereof.

(b) In the event of any instituted or asserted Third Party Claim against an Indemnified Party, the Indemnified Party shall promptly cause written notice of the assertion of any Third Party Claim of which it has knowledge which is covered by the provisions of Section 6.1(a) or Section 6.1(b), as applicable, to be forwarded to the Indemnifying Party. The failure to give such notification or any deficiency in such notification will not relieve such Indemnifying Party from any obligation under this ARTICLE 6, except (i) to the extent such failure to give such notification or such deficiency in such notification actually and materially prejudices such Indemnifying Party or (ii) as provided in Section 6.3. The Indemnifying Party shall have the right, at its sole option and expense, to be represented by counsel reasonably acceptable to the Indemnified Party and to defend against, negotiate, settle or otherwise deal with any Third Party Claim which relates to any Losses indemnified by it hereunder, subject to the provisions below; *provided*, *however*, that the Indemnifying Party may not assume control of defense to (or, following such assumption of control in accordance herewith, may not continue to control such defense of, as applicable) a Third Party Claim (i) unless it covenants to the Indemnified Party in writing within ten (10) Business Days after the Indemnified Party has given notice of the Third Party Claim to the Indemnifying Party to indemnify, defend and hold harmless the Indemnified Party from and against the entirety of any and all Losses that the Indemnified Party may suffer resulting from or arising out of the Third Party Claim (subject, however, to the limitations set forth in Section 6.6), (ii) in which equitable relief other than monetary damages is sought, (iii) if such Third Party Claim is brought by a Governmental Entity or is otherwise related to or arises in connection with any FDA, Tax or criminal or regulatory enforcement matter, (iv) if the Indemnified Party has been advised in writing by outside counsel that a legal conflict or potential legal conflict exists between the Indemnified Party and the Indemnifying Party in connection with conducting the defense of the Third Party Claim, (v) if settlement of, an adverse Judgment with respect to, or conduct of the defense of the Third Party Claim by the Indemnifying Party is, in the good faith judgment of the Indemnified Party, likely to be materially adverse to the Indemnified Party's or its Affiliates' reputation or continuing business interests (including its relationships with current or potential customers, licensors, distributors, suppliers, or other parties material to the conduct of its business), or (vi) the Indemnifying Party fails to diligently and vigorously and in good faith conduct the defense of the Third Party Claim.

(c) If the Indemnifying Party elects not to defend against, negotiate, settle or otherwise deal with any Third Party Claim that relates to any Losses indemnified against hereunder, or is not permitted to assume the defense (or, following such assumption of the defense in accordance herewith, is not permitted to continue to control such defense, as applicable) of a Third Party Claim pursuant to the proviso to the third sentence of Section 6.2(b), the Indemnified

Party may defend against, negotiate, settle or otherwise deal with such Third Party Claim, subject to the provisions below. If the Indemnifying Party shall assume the defense of any Third Party Claim pursuant to the terms of this Agreement, the Indemnified Party may participate, at its own expense, in the defense of such Third Party Claim; *provided*, *however*, that such Indemnified Party shall be entitled to participate in any such defense with separate counsel at the expense of the Indemnifying Party if (i) so requested by the Indemnifying Party to participate or (ii) in the written opinion of outside counsel to the Indemnified Party a legal conflict or potential legal conflict exists between the Indemnified Party and the Indemnifying Party that would make such separate representation advisable. The Parties agree to reasonably cooperate with each other in connection with the defense, negotiation or settlement of any such Third Party Claim. Notwithstanding anything in this Section 6.2 to the contrary, the Indemnifying Party shall not, without the prior written consent of the Indemnified Party, settle or compromise any Third Party Claim or permit a default or consent to entry of any Judgment unless (A) the claimant provides to the Indemnified Party a full, general and unqualified release of the Indemnified Parties and their respective Affiliates and Representatives from all liability in respect of such Third Party Claim, (B) such settlement does not involve any injunctive relief binding upon the Indemnified Party or any of its Affiliates or Representatives, (C) such settlement does not create an Encumbrance upon any of the assets of any Indemnified Party or impose any restriction or condition that would apply to or materially affect any Indemnified Party or the conduct of any Indemnified Party's business, and (D) such settlement does not involve any admission of liability or wrongdoing by any Indemnified Party or any of its Affiliates or Representatives.

6.3 Survival. The representations and warranties of Seller and Buyer under this Agreement, and liability for the breach thereof, shall survive the Effective Date and shall remain in full force and effect for a period of two (2) years following the Effective Date; *provided*, *however*, that all covenants (including Section 5.6), the Fundamental Representations and any claims for fraud shall survive the Effective Date and shall remain in full force and effect until the later of (a) six (6) years following the Effective Date and (b) the expiration of the applicable statute of limitations. No claim for breach of any representation, warranty, covenant or agreement may be brought after expiration of the survival periods set forth in this Section 6.3. Notwithstanding the foregoing, if written notice of a claim has been given in the manner required by Section 6.2 prior to the expiration of the applicable survival period by the Party seeking indemnification for such claim, then the relevant covenants, representations and warranties of the other Party shall survive as to such claim until such claim has been finally resolved pursuant to this ARTICLE 6.

6.4 Additional Indemnification Matters. The right of indemnification provided under this ARTICLE 6 shall not be affected by any knowledge acquired (or capable of being acquired) at any time, whether before or after the Effective Date, with respect to the accuracy or inaccuracy of, or compliance or noncompliance with, any representation, warranty, covenant, or agreement contained herein.

6.5 Adjustments. Any amount paid under this ARTICLE 6 shall be treated as an adjustment to the Purchase Price for all Tax purposes unless otherwise required by applicable Law.

6.6 Limitations of Liability.

(a) Notwithstanding anything to the contrary contained in this Agreement (but subject to Section 6.6(b)), (i) each Party's maximum aggregate liability to the other Party arising out of or in any way related to this Agreement (including pursuant to this ARTICLE 6) shall not exceed an amount equal to the Purchase Price and (ii) except to the extent actually awarded against a Buyer or Seller Indemnified Party pursuant to a Judgment with respect to a Third Party Claim and except for a Party's fraud, then, in each case of this clause (ii), no Party shall have any liability under any provision of this Agreement for any punitive, incidental, consequential, special or indirect damages, including business interruption, diminution of value, loss of future revenue, profits or income, or loss of business reputation or opportunity relating to the breach or alleged breach of this Agreement [*], regardless of the legal theory under which such liability or obligation may be sought to be imposed, whether sounding in contract or tort, or whether at law or in equity, or otherwise.

(b) Nothing in Section 6.6(a) or Section 6.7, shall operate to limit or exclude in any way Seller's liability for any and all Excluded Liabilities.

6.7 [*].

ARTICLE 7
GENERAL PROVISIONS TC "ARTICLE 7 GENERAL PROVISIONS" \F C \L "1"

7.1 Notice Requirements. Any notice, request, demand, waiver, consent, approval, or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if (a) delivered by hand, (b) sent by internationally recognized overnight delivery service that maintains records of delivery, addressed to the Parties at their respective addresses specified in this Section 7.1 or to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Section 7.1, or (c) sent via email. Such notice shall be deemed to have been given (i) as of the date delivered by hand, (ii) on the second Business Day (at the place of delivery) after deposit with an internationally recognized overnight delivery service, or (iii) on the first Business Day following successful transmission via email.

If to Buyer, to:

[*]

with a copy (which shall not constitute notice) to:

[*]

If to Seller to:

Seller

Day One Biopharmaceuticals, Inc.

2000 Sierra Point Parkway, Suite 501
Brisbane, CA 94005
Attention: [*]
Emails: [*]

with a copy (which shall not constitute notice) to:

Fenwick and West, LLP

555 California Street, 12th Floor

San Francisco, CA 94104

Attention: [*]

Emails: [*]

7.2 Construction. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word “or” is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend, or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term “including,” “include,” or “includes” as used herein shall mean “including, but not limited to,” and shall not limit the generality of any description preceding such term. The words “will” and “shall” have the same meaning. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party hereto. Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provisions.

7.3 References. Unless otherwise specified, (a) references in this Agreement to any Article, Section, Schedule or Exhibit shall mean references to such Article, Section, Schedule or Exhibit of this Agreement, (b) references in any Section to any clause are references to such clause of such Section, and (c) references to any agreement, instrument, or other document in this Agreement refer to such agreement, instrument, or other document as originally executed or, if subsequently amended, replaced, or supplemented from time to time, as so amended, replaced, or supplemented and in effect at the relevant time of reference thereto.

7.4 Entire Agreement; Amendments. This Agreement, the documents, Exhibits, and Schedules referred to herein, and the Confidentiality Agreement sets forth and constitutes the

entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understandings, promises, and representations, whether written or oral, with respect thereto are superseded hereby. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth in this Agreement. No amendment, modification, release, or discharge shall be binding upon the Parties unless in writing and duly executed by authorized Representatives of both Parties.

7.5 Assignment. Without the prior written consent of the other Party, neither Party shall sell, transfer, assign, delegate, pledge, or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Agreement or any of its rights or duties hereunder; *provided* that (a) either Party may make such a sale, transfer, assignment, delegation, pledge or other disposal without the other Party's consent to any of its Affiliates and (b) Buyer may make such a sale, transfer, assignment, delegation, pledge or disposal, in whole or in part, without Seller's consent, to any purchaser, transferee, or assignee of the Purchased Assets. With respect to any permitted assignment, the assigning Party shall remain responsible for the performance by such permitted assignee of the assigning Party's duties and obligations hereunder. Any attempted sale, transfer, assignment, delegation, pledge or other disposal in violation of this Section 7.5 shall be null and void and of no effect. All validly assigned and delegated rights and obligations of the Parties hereunder shall be binding upon and inure to the benefit of and be enforceable by and against the successors and permitted assigns of Buyer or Seller, as the case may be.

7.6 Severability. If any provision of this Agreement is held to be illegal, invalid, or unenforceable under any present or future law, and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby (a) such provision shall be fully severable; (b) this Agreement shall be construed and enforced as if such illegal, invalid, or unenforceable provision had never comprised a part hereof; (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid, or unenforceable provision or by its severance herefrom; and (d) in lieu of such illegal, invalid, or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid, and enforceable provision as similar in terms to such illegal, invalid, or unenforceable provision as may be possible and reasonably acceptable to the Parties. To the fullest extent permitted by applicable Law, each Party hereby waives any provision of Law that would render any provision hereof illegal, invalid, or unenforceable in any respect.

7.7 Governing Law. This Agreement or the performance, enforcement, breach or termination hereof shall be interpreted, governed by and construed in accordance with the laws of the State of New York, United States, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

7.8 Submission to Jurisdiction. Each Party irrevocably agrees that any legal action or proceeding arising out of or relating to this Agreement brought by such Party or its successors or assigns shall be brought and determined in any New York state or federal court, and each Party hereby irrevocably (a) submits to the exclusive jurisdiction of the aforesaid courts with regard to any such action or proceeding arising out of or relating to this Agreement and the transactions

contemplated hereby and (b) agrees that service of any court paper may be made in the manner provided for in Section 7.1 or such other manner as may be provided under applicable Laws or court rules governing service of process. Each Party agrees not to commence any action, suit or proceeding relating thereto except in the courts described above in New York, other than actions in any court of competent jurisdiction to enforce any judgment, decree or award rendered by any such court in New York as described herein. Each Party hereby irrevocably and unconditionally waives, and agrees not to assert, by way of motion or as a defense, counterclaim or otherwise, in any action or proceeding arising out of or relating to this Agreement or the transactions contemplated hereby, (i) any claim that it is not personally subject to the jurisdiction of the courts in New York as described herein for any reason, (ii) that it or its property is exempt or immune from jurisdiction of any such court or from any legal process commenced in such courts (whether through service of notice, attachment prior to judgment, attachment in aid of execution of judgment, execution of judgment or otherwise), and (iii) that (A) the suit, action or proceeding in any such court is brought in an inconvenient forum, (B) the venue of such suit, action or proceeding is improper, or (C) this Agreement, or the subject matter hereof, may not be enforced in or by such courts.

7.9 WAIVER OF JURY TRIAL. EACH PARTY, TO THE EXTENT PERMITTED BY LAW, KNOWINGLY, VOLUNTARILY, AND INTENTIONALLY WAIVES ITS RIGHT TO A TRIAL BY JURY IN ANY ACTION OR OTHER LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT AND THE TRANSACTIONS IT CONTEMPLATES. THIS WAIVER APPLIES TO ANY ACTION OR LEGAL PROCEEDING, WHETHER SOUNDING IN CONTRACT, TORT, OR OTHERWISE.

7.10 Waiver and Non-Exclusion of Remedies.

(a) Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party hereto of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise, and nothing in this Agreement shall be deemed a waiver by any Party of any right to specific performance or injunctive relief. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by applicable Law or otherwise available except as expressly set forth herein.

(b) The Parties agree that irreparable harm would occur in the event that the transactions contemplated hereby are not consummated in accordance with the terms of this Agreement, and that money damages or other legal remedies would not be an adequate remedy for any such harm. Accordingly, the Parties acknowledge and hereby covenant and agree that in the event of any breach or threatened breach of the covenants, agreements, or obligations set forth in this Agreement, then in addition to any other remedy available at law or in equity, the non-breaching Party will be entitled to seek an injunction or injunctions to prevent or restrain any breaches or threatened breaches of this Agreement, and to specifically enforce the terms and provisions of this Agreement to enforce compliance with the covenants, agreements, and

obligations under this Agreement. Each Party hereby covenants and agrees not to raise, and irrevocably waives, any objections to the availability of such relief that a remedy at law would be adequate and that a bond or other security will be required.

7.11 No Benefit to Third Parties. Except as provided in ARTICLE 6, the covenants and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they shall not be construed as conferring any rights on any other Persons.

7.12 Counterparts; Execution. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one (1) and the same instrument. This Agreement may be executed by electronically transmitted signatures and such signatures shall be deemed to bind each Party hereto as if they were original signatures.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, each of Buyer and Seller has caused this Agreement to be executed and delivered by their respective officers thereunto duly authorized, all as of the date first written above.

BUYER

[*]

By: _____
Name: [*]
Title: [*]

[*Signature Page to Asset Purchase Agreement*]

IN WITNESS WHEREOF, each of Buyer and Seller has caused this Agreement to be executed and delivered by their respective officers thereunto duly authorized, all as of the date first written above.

SELLER

DAY ONE BIOPHARMACEUTICALS, INC.

By: /s/ Jeremy Bender
Name: Jeremy Bender
Title: Chief Executive Officer

[*Signature Page to Asset Purchase Agreement*]

Exhibit A

Approval Letter

[Copy to be attached]

Exhibit B

Viracta Payment and Release Letter

[Copy to be Attached]

Exhibit 2.3(b)

Form of Seller Cover Letter

[Day One Biopharmaceuticals, Inc. Letterhead]

Priority Review Voucher Transfer May __, 2024

[●]

Re: Ojemda (tovorafenib) Tablet
NDA 217700, SN:[●]
Transfer of Rare Pediatric Disease Priority Review Voucher PRV NDA 217700

Dear [●]:

Reference is made to the New Drug Application (NDA) 217700, the approval letter dated April 23, 2024 (the "***Approval Letter***") (Ref ID: 5368906) reflecting the grant of the Rare Pediatric Disease Priority Review Voucher PRV NDA 217700 (the "***Voucher***") to Day One Biopharmaceuticals, Inc. ("Day One") in connection with the U.S. Food and Drug Administration's ("FDA's") approval of New Drug Application Number 217700 for Ojemda (tovorafenib) Tablet.

Please be advised that, effective as of May __, 2024, Day One has transferred complete ownership of the Voucher to [*], and [*] has legally accepted complete ownership of the Voucher from Day One. Day One and [*] have exchanged letters acknowledging the transfer, copies of which are enclosed herein.

If you have any questions or need clarification regarding this submission, please do not hesitate to contact me using the following information:

Email: [*]
Office: [*]
Cell: [*]

Sincerely,

[*]
Sr. Director Regulatory Science
Day One Biopharmaceuticals, Inc.

Exhibit 2.4(a)

Form of Bill of Sale

BILL OF SALE

This BILL OF SALE (the "***Bill of Sale***") is made and entered into as of May 29, 2024, by and between [*] ("***Buyer***") and Day One Biopharmaceuticals, Inc., a Delaware corporation ("***Seller***"). Buyer and Seller may hereinafter be referred to individually as a "***Party***" and collectively as the "***Parties***". Reference is made to that certain Asset Purchase Agreement, dated as of May 29, 2024 by and between the Parties (the "***Purchase Agreement***"). Capitalized terms used but not otherwise defined herein shall have the meanings assigned to them in the Purchase Agreement.

WHEREAS, the Parties have entered into the Purchase Agreement, pursuant to which Seller has agreed to sell to Buyer, and Buyer has agreed to purchase from Seller, upon the terms and conditions set forth in the Purchase Agreement, all right, title, and interest of Seller in and to the Purchased Assets.

NOW, THEREFORE, in consideration of the premises and covenants hereinafter contained and the representations, warranties, and covenants contained in the Purchase Agreement, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Buyer and Seller, intending to be legally bound, hereby agree as follows:

1. Effective Time. This Bill of Sale shall be effective as of the Effective Date.

2. Transfer of the Purchased Assets. Effective as of the Effective Date, pursuant to the terms and subject to the conditions of the Purchase Agreement, Seller (on behalf of itself and its Affiliates) hereby irrevocably sells, assigns, transfers, conveys and delivers to Buyer and its successors and its assigns, and Buyer hereby does purchase from Seller, all of Seller's and its Affiliates' right, title and interest in and to the Purchased Assets (including the Priority Review Voucher), in each case free and clear of all Encumbrances.

3. Binding Effect; Amendments. This Bill of Sale shall be binding upon, inure to the benefit of, and be enforceable by, the Parties and their respective legal representatives, successors and permitted assigns. Neither this Bill of Sale, nor any term or provision hereof, may be amended, modified, superseded, or cancelled except by an instrument in writing signed by each Party hereto.

4. Governing Law. This Bill of Sale or the performance, enforcement, breach or termination hereof shall be interpreted, and governed by the rules set forth in Sections 7.7, 7.8, and 7.9 of the Purchase Agreement. In the event of any conflict between the terms of this Bill of Sale and the Purchase Agreement, the Purchase Agreement shall control.

5. Counterparts. This Bill of Sale may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one (1) and the same instrument. This Bill of Sale may be executed by

electronically transmitted signatures and such signatures shall be deemed to bind each Party hereto as if they were original signatures.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, each of Buyer and Seller has caused this Bill of Sale to be executed and delivered by their respective officers thereunto duly authorized, all as of the date first written above.

BUYER

[*]

By: _____
Name: [*]
Title: [*]

SELLER

DAY ONE BIOPHARMACEUTICALS, INC.

By: /s/ Jeremy Bender
Name: Jeremy Bender
Title: Chief Executive Officer

[*Signature Page to Bill of Sale*]

Exhibit 2.4(b)

Form of Seller PRV Transfer Letter

[Day One Biopharmaceuticals, Inc. Letterhead]

May 29, 2024

[*]

Re: NDA 217700 – Transfer of Rare Pediatric Disease Priority Review Voucher PRV NDA 217700 (the "***Voucher***")

Dear Sir or Madam:

Reference is made to the above-referenced NDA approval letter dated April 23, 2024 reflecting the grant of the Voucher to Day One Biopharmaceuticals, Inc. ("***Seller***") in connection with the U.S. Food and Drug Administration's ("FDA's") approval of New Drug Application Number 217700 for Ojemda (tovorafenib) Tablet.

Seller hereby irrevocably transfers ownership of the Voucher to [*] ("**Buyer**"), and Buyer has legally accepted complete ownership of the Voucher from Seller.

This letter of transfer will be presented to the FDA by, or on behalf of, Buyer as evidence that Seller has transferred the Voucher to Buyer. Together with the acknowledgment of transfer letter from Buyer to Seller dated May 29, 2024, these letters serve as a complete record of transfer of the Voucher from Seller to Buyer.

Sincerely,

[*]
Sr. Director, Regulatory Science

Exhibit 2.5(d)

Form of Buyer PRV Transfer Letter

[[*] Letterhead]

May 29, 2024

Day One Biopharmaceuticals, Inc.
2000 Sierra Point Parkway, Suite 501
Brisbane, CA 94005
Attention: Adam Dubow and Sishir Mokkapati

Re: NDA 217700 – Acknowledgment of Transfer of Rare Pediatric Disease Priority Review Voucher PRV NDA 217700 (the "***Voucher***")

Dear Sir or Madam:

Reference is made to the above-referenced NDA approval letter dated April 23, 2024 reflecting the grant of the Voucher to Day One Biopharmaceuticals, Inc. ("***Seller***") in connection with the U.S. Food and Drug Administration's ("FDA's") approval of New Drug Application Number 217700 for Ojemda (tovorafenib) Tablet.

This letter acknowledges and records that, as of May 29, 2024, [*] ("**Buyer**") has legally accepted complete ownership of the Voucher from Seller.

This letter will be presented to the FDA by, or on behalf of, Buyer as evidence that Buyer acknowledges and accepts the transfer of the Voucher from Seller to Buyer. Together with the letter of transfer from Seller to Buyer dated May 29, 2024, these letters serve as a complete record of transfer of the Voucher from Seller to Buyer.

Sincerely,

_____

[*]

Exhibit 10.2

CONFIDENTIAL

Execution Version

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO DAY ONE BIOPHARMACEUTICALS, INC. IF PUBLICLY DISCLOSED.

EXCLUSIVE LICENSE AGREEMENT

BY AND BETWEEN

MABCARE THERAPEUTICS
(上海麦科思生物医药有限公司)

AND

DAY ONE BIOPHARMACEUTICALS, INC.

JUNE 17, 2024

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Execution Version

EXCLUSIVE LICENSE AGREEMENT

This **Exclusive License Agreement** ("**Agreement**") is entered into as of June 17, 2024 (the "**Effective Date**"), by and between MabCare Therapeutics (上海麦科思生物医药有限公司), a company incorporated under the law of the People's Republic of China, located at 3F, Building 1, No. 368, Xiaonan Road, Fengxian District, Shanghai, China 201401 ("**MabCare**") and Day One Biopharmaceuticals, Inc., a Delaware corporation located at 395 Oyster Point Boulevard, Suite 217, South San Francisco, CA 94080, USA ("**Day One**"). MabCare and Day One may be referred to in this Agreement individually as a "**Party**" or collectively as the "**Parties**."

BACKGROUND

WHEREAS, MabCare has developed a proprietary antibody drug conjugate targeting PTK7, and owns or controls certain intellectual property rights relating thereto;

WHEREAS, Day One is a biotechnology company with expertise in researching, developing and commercializing targeted therapies to treat cancer; and

WHEREAS, Day One wishes to obtain from MabCare an exclusive license to develop, manufacture and commercialize Licensed Compounds and Licensed Products (in each case as defined herein) in certain countries, and MabCare is willing to grant such license to Day One in accordance with the terms and conditions set forth herein.

NOW THEREFORE, in consideration of the mutual covenants and agreements contained herein, and other good and valuable consideration, the sufficiency of which is hereby acknowledged by both Parties, the Parties agree as follows:

ARTICLE 1
DEFINITIONS & INTERPRETATION

Whenever used in this Agreement with an initial capital letter, the terms defined in this Article 1 and elsewhere in this Agreement, and any cognates or correlatives thereof, whether used in the singular or plural, shall have the meanings specified.

1.1"**Abmart Agreement**" means that certain "PTK7 antibody and cell line property rights purchase contract" by and between MabCare and Abmart Pharmaceutical Technology (Shanghai) Co., Ltd. dated August 18, 2022.

1.2"**Accounting Standards**" means GAAP, IAS/IFRS or equivalent accounting standards consistently applied by the applicable Party or other entity in maintaining its books and records.

1.3"**Achieved Development/Commercial Milestone**" has the meaning set forth in Section 6.2.

1.4"**Acquirer**" means a Third Party that acquires a Party through a Change of Control of such Party, together with any Affiliates of such Third Party existing immediately prior to the

consummation of the Acquisition. For clarity, an "Acquirer" of a Party shall exclude the Party and all of its Affiliates existing immediately prior to the consummation of the Acquisition.

1.5"**Acquirer Program**" has the meaning set forth in Section 2.9.2.

1.6"**Acquired Program**" has the meaning set forth in Section 2.9.2.

1.7 "**Affiliate**" means, with respect to a Party, any entity directly or indirectly controlling, controlled by or under common control with such Party, but only for so long as such control exists. For purposes of this definition, "control" (including, with correlative meanings, "controlled by," "controlling" and "under common control with") means (a) possession, direct or indirect, of the power to direct or cause direction of the management or policies of an entity, whether through ownership of securities or other ownership interests, by contract or otherwise, or (b) direct or indirect ownership of more than fifty percent (50%) (or the maximum ownership interest permitted by Applicable Law giving control) of the voting securities or other ownership or general partnership interest or other comparable equity interests in an entity.

1.8"**ADC**" means a molecule consisting of (a) an antibody Directed To a target and (b) a Payload, wherein the [*]

1.9"**Applicable Laws**" means any and all laws, regulations, ordinances, decrees, judicial and administrative orders (and any license, franchise, permit or similar right granted under any of the foregoing) and any other requirements of any applicable Governmental Authority that govern or otherwise apply to a Party's activities in connection with this Agreement.

1.10"**Biosimilar Product**" means, with respect to a Licensed Product, any product that (a) is sold by a Third Party that is not, or not authorized by, an Affiliate, (direct or indirect) licensee, distributor or Sublicensee of Day One or any of its Affiliates and (b) is approved as a "biosimilar", "interchangeable" or "similar biological medicinal product" (or a foreign equivalent) of the Licensed Product in such country in reliance, in whole or in part, on the prior approval (or on safety or efficacy data submitted in support of the prior approval) of the Licensed Product as determined by the applicable Regulatory Authority, including any product authorized for sale (i) in the U.S. pursuant to 42 U.S.C §262(k), (ii) in the European Union pursuant to a provision of Articles 10, 10a or 10b of Parliament and Council Directive 2001/83/EC as amended (including an application under Article 6.1 of Parliament and Council Regulation (EC) No 726/2004 that relies for its content on any such provision), or (iii) in any other country or jurisdiction pursuant to all equivalents of such provisions, including any amendments and successor statutes with respect to the subsections (i) through (iii) thereto.

1.11"**Business Day**" means a day other than any Saturday, Sunday or other day on which banking institutions in New York, New York or Beijing, China are authorized or required by Applicable Laws to remain closed.

1.12"**Calendar Quarter**" means any of the three (3) consecutive calendar month periods beginning on January 1, April 1, July 1 or October 1 of any year, except that the first Calendar Quarter shall commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date, and the last

Calendar Quarter shall end on the last day of the Term.

1.13"**Calendar Year**" means any of the twelve (12) consecutive calendar month periods beginning on January 1 and ending on December 31, except that the first Calendar Year shall commence on the Effective Date and end on the first December 31 to occur after the Effective Date, and the last Calendar Year shall end on the last day of the Term.

1.14"**CB-002**" means (a) MabCare's proprietary ADC Directed To PTK7 referred to as "CB-002" (also sometimes referred to as "MTX-13") and consisting of MabCare's proprietary antibody "Ab13" conjugated to Exatecan, as described in more detail in Schedule 1.14, or (b) to the extent applicable, any Licensed Compound other than CB-002 that becomes Controlled by MabCare during the Term and licensed to Day One pursuant to this Agreement.

1.15"**CB-002 Product**" means any product containing or comprising CB-002 all forms, presentations, formulations, methods of administration and dosage forms.

1.16"**CDA**" has the meaning set forth in Section 7.4.

1.17"**Cell Line Agreement**" has the meaning set forth in Section 5.4.

1.18"**Cessation Period**" has the meaning set forth in Section 11.6.

1.19"**Change of Control**" means, with respect to a Party (or the parent or controlling Affiliate to such Party), that any of the following events has occurred after the Effective Date:

1.19.1any "person" or "group" (as such terms are defined below): (a) is or becomes the "beneficial owner" (as defined below), directly or indirectly, of shares of capital stock or other interests (including partnership interests) of such Party then outstanding and normally entitled (without regard to the occurrence of any contingency) to vote in the election of the directors, managers or similar supervisory positions ("**Voting Stock**") of such Party representing fifty percent (50%) or more of the total voting power of all outstanding classes of Voting Stock of such Party; or (b) has the power, directly or indirectly, to elect a majority of the members of the Party's board of directors, or similar governing body ("**Board of Directors**");

1.19.2such Party enters into a merger, consolidation, or similar transaction with another Person (whether or not such Party is the surviving entity) and as a result of such merger, consolidation, or similar transaction: (a) the members of the Board of Directors of such Party immediately prior to such transaction constitute less than a majority of the members of the Board of Directors of such Party or such surviving Person immediately following such transaction; or (b) the Persons that beneficially owned, directly or indirectly, the shares of Voting Stock of such Party immediately prior to such transaction cease to beneficially own, directly or indirectly, shares of Voting Stock of such Party representing at least a majority of the total voting power of all outstanding classes of Voting Stock of the surviving Person;

1.19.3the sale, transfer, or disposition of all or substantially all of the assets of such Party to a Third Party in a transaction or series of transactions; or

1.19.4the holders of capital stock of such Party approve a plan or proposal for the

liquidation or dissolution of such Party.

For the purpose of this definition of Change of Control: (a) “person” and “group” have the meanings given such terms under Section 13(d) and 14(d) of the United States Securities Exchange Act of 1934 and the term “group” includes any group acting for the purpose of acquiring, holding, or disposing of securities within the meaning of Rule 13d-5(b)(1) under the said Act; (b) a “beneficial owner” shall be determined in accordance with Rule 13d-3 under the aforesaid Act; and (c) the terms “beneficially owned” and “beneficially own” shall have meanings correlative to that of “beneficial owner.”

1.20“**Clinical Supply Agreement**” has the meaning set forth in Section 5.2.

1.21“**Clinical Trial**” means a clinical study (or a portion thereof) involving the administration of a pharmaceutical or biological product to a human.

1.22“**CMC**” means chemistry, manufacturing and controls.

1.23“**CMO**” means a Third Party contract manufacturing organization.

1.24 “**Combination Product**” means a Licensed Product that (a) contains one (1) or more therapeutically or prophylactically active compound(s) or ingredients (excluding formulation components such as coatings, stabilizers, excipients, solvents or controlled release technologies) that are not Licensed Compound(s) (each, an “**Additional Active**”), or (b) is co-packaged or combined with one (1) or more Additional Actives and sold for a single price.

1.25“**Commercialize**” means any and all activities directed to the offering for sale and sale of a product, including activities directed to marketing, promoting, advertising, detailing, storing, distributing, importing, exporting, selling and offering to sell (including receiving, accepting, and filling orders), booking and recording sales, and interacting with Regulatory Authorities regarding any of the foregoing, including seeking Pricing and Reimbursement Approvals. For the avoidance of doubt, the right to Commercialize a product will include the right to make, have made, use, sell, offer for sale, and import such product for the purposes set forth above.

1.26“**Commercially Reasonable Efforts**” means[*].

1.27“**Competing Product**” means [*].

1.28“**Competitive Infringement**” has the meaning set forth in Section 8.6.1.

1.29“**Confidential Information**” has the meaning set forth in Section 7.1.

1.30 “**Control**” or “**Controlled**” means, subject to Section 2.7 and Section 12.1.2, with respect to any Know-How, Regulatory Materials, Patent Rights, or other rights, the possession by a Party or any of its Affiliates of the legal authority or right (whether by ownership, license or otherwise, other than by operation of the licenses and other grants in this Agreement) to grant to the other Party a license, sublicense, right to use or right to access such Know-How, Regulatory Material, Patent Right, or other right as provided herein without violating the terms of any

agreement or other arrangement with any Third Party existing at the time such Party would be required hereunder to grant the other Party such license, sublicense, right to use or right to access. All Know-How and Patent Rights licensed to MabCare under the Hyslink License Agreement are hereby deemed "Controlled" by MabCare during the term thereof. With respect to any Know-How and Patent Rights that would otherwise be Controlled by a Party through an in-license with a Third Party entered into after the Effective Date, for which payments are due to such Third Party, such Know-How or Patent Rights shall not be deemed to be "Controlled" by such Party unless the other Party agrees to pay for such amount attributable to its Development, Manufacture, Commercialization or other exploitation of the Licensed Compounds and Licensed Products as set forth in this Agreement.

1.31"**Cover**" means, with respect to given product (or component thereof), process or method and Patent Right, that a Valid Claim of such Patent Right would, absent a license thereunder or ownership thereof, be infringed by the making, having made, use, sale, offer for sale or importation of such product, component, process or method, and for purposes of determining such infringement, considering claims of pending patent applications as Valid Claims (to the extent such claims would otherwise constitute Valid Claims) as if they have already been issued.

1.32"**Data**" means all CMC information, preclinical data, clinical data and safety data, in each case generated by or on behalf of a Party, or its Affiliates or their respective (sub)licensees, in the course of performing activities under this Agreement in connection with the Development or Manufacture of CB-002 Products. For clarity, Data does not include any patentable Foreground Know-How.

1.33"**Data Protection Laws**" has the meaning set forth in Section 9.3.1.

1.34"**Day One Background Know-How**" means [*].

1.35"**Day One Background Patents**" means [*].

1.36 "**Day One Background Technology**" means the Day One Background Know-How and the Day One Background Patents.

1.37"**Day One Development Plan**" has the meaning set forth in Section 4.4.1.

1.38 "**Day One Foreground Know-How**" means any and all Foreground Know-How generated, developed, conceived or reduced to practice solely by or on behalf of Day One or its Affiliates.

1.39"**Day One Foreground Patents**" means any and all Patent Rights that claim any Day One Foreground Know-How.

1.40"**Day One Indemnitee**" has the meaning set forth in Section 10.2.

1.41"**Day One Know-How**" means any and all (a) Day One Foreground Know-How [*], and (b) Day One Background Know-How.

1.42"**Day One Patents**" means any and all (a) Day One Foreground Patents [*], and

(b) Day One Background Patents. [*]

1.43"**Day One Technology**" means the Day One Patents and Day One Know-How.

1.44"**Day One Territory**" means worldwide, excluding the MabCare Territory.

1.45"**Develop**" means any and all pre-clinical, non-clinical and clinical research and development activities for a compound or product, including research activities, modification and optimization activities, preclinical studies, Clinical Trials, toxicology, pharmacokinetic, pharmacodynamic, drug-drug interaction, safety, tolerability and pharmacological studies, supply of compound or product for use in the foregoing activities (including placebos and comparators), statistical analyses, the preparation and submission of INDs, MAAs and other Regulatory Submissions for the purpose of obtaining, registering and maintaining Regulatory Approval of such compound or product, as well all interactions with Regulatory Authorities with respect to the foregoing. For the avoidance of doubt, the right to Develop a compound or product will include the right to make, have made, use and import such compound or product for the purposes set forth above.

1.46"**Development/Commercial Milestone Event**" has the meaning set forth in Section 6.2.

1.47"**Development/Commercial Milestone Payment**" has the meaning set forth in Section 6.2.

1.48"**Development Dispute**" has the meaning set forth in Section 3.3.1.

1.49"**Development Plan**" has the meaning set forth in Section 4.4.1.

1.50 "**Directed To**" means, with respect to an ADC and an antigen or other protein target, that the antibody component of such ADC binds selectively to such antigen or protein target with specificity.

1.51"**Dispute**" has the meaning set forth in Section 12.5.1.

1.52"**Distributor**" means any Third Party that purchases Licensed Product from a Party, its Affiliates or Sublicensees (or (sub)licensees in the case of MabCare) for resale in the Territory and that takes title to such Licensed Product. For clarity, a "Distributor" shall not be considered a Sublicensee (or (sub)licensees in the case of MabCare) for purposes of this Agreement even if (sub)licenses are granted to such Distributor for purposes of conducting its resale activities.

1.53"**DPA**" has the meaning set forth in Section 9.3.1.

1.54"**Electronic Delivery**" has the meaning set forth in Section 12.15.

1.55"**Enforcement Action**" has the meaning set forth in Section 8.6.2.

1.56"**Europe Countries**" means the United Kingdom, France, Germany, Spain and

Italy.

1.57 "**European Union**" or "**EU**" means the member states of the European Union as they exist at the time of reference.

1.58 "**Executive Officers**" means a senior executive of a Party having corporate authority to make decisions regarding this Agreement.

1.59"**Existing Agreements**" means the Abmart Agreement and Hyslink License Agreement.

1.60"**Existing Inventory**" has the meaning set forth in Section 4.1.3.

1.61"**Expert**" has the meaning set forth in Section 3.3.1.

1.62"**FDA**" means the United States Food and Drug Administration or any successor entity thereto.

1.63"**FFDCA**" means the United States Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., as may be amended from time to time.

1.64"**Field**" means all uses in humans.

1.65"**First Commercial Sale**" means, with respect to a Licensed Product, the first sale of such Licensed Product by or on behalf of Day One, its Affiliates, or Sublicensees to a Third Party for distribution, use or consumption in a country in the Territory after all Regulatory Approvals have been obtained for such Licensed Product in such country. Notwithstanding the foregoing, Licensed Product provided for: (a) research and Clinical Trial purposes prior to or in support of Regulatory Approval; (b) compassionate use, named patient sales, patient assistance programs, in each case, that are not intended for general use or sale of such Licensed Product without Regulatory Approval; (c) test marketing programs or other similar programs or studies, or for sample or promotional purposes (provided that the Licensed Product is not otherwise generally available for purchase in the applicable country, and are provided at no cost or below cost); or (d) early access programs that are not intended for general use or sale of such Licensed Product without Regulatory Approval, in each case ((a) – (d)), shall not constitute a First Commercial Sale of such Licensed Product. In addition, transfers of Licensed Product by and between Day One, its Affiliates or Sublicensees shall not constitute a First Commercial Sale.

1.66"**Force Majeure**" has the meaning set forth in Section 12.6.

1.67"**Foreground Know-How**" means any and all Know-How, whether or not patentable, that is generated, created, developed, conceived, reduced to practice or otherwise made during the Term (a) solely by or on behalf of a Party or any of its Affiliates or (b) jointly by or on behalf of MabCare or any of its Affiliates and Day One or any of its Affiliates, in each case ((a) and (b)) in the course of performing activities or exercising rights under this Agreement.

1.68"**Foreground Patents**" means any and all Patent Rights that claim Foreground Know-How.

1.69"**Full Registrational Study**" means a Clinical Trial of a product that is intended to (a) obtain sufficient efficacy and safety data in patients with the indication being studied to obtain Regulatory Approval of such product for such indication in the relevant country or jurisdiction, and (b) define contraindications, warnings, precautions and adverse reactions that are associated with such product in the dosage range to be prescribed for such indication, including the trials referred to in 21 C.F.R. §312.21(c), as amended, regardless of whether the sponsor of such Clinical Trial characterizes or refers to such Clinical Trial (e.g., as a "Phase 3," "Phase 2b" or "Phase 2/3" Clinical Trial) in the applicable protocol, on clinicaltrials.gov, or in any other context.

1.70"**GAAP**" means accounting principles generally accepted in the United States, consistently applied.

1.71"**GCP**" means the applicable then-current standards for clinical activities for pharmaceuticals or biologicals, as set forth in the FFDCA and any regulations or guidance documents promulgated thereunder, as amended from time to time, together with, with respect to work performed in a country other than the United States, any similar standards of good clinical practice as are required by any Regulatory Authority in such country.

1.72 "**Genomeditech Agreement**" means the purchase agreement (together with the product manual) between Genomeditech (吉满生物科技（上海）有限公司) ("**Genomeditech**") and MabCare, dated October 8, 2023.

1.73"**GLP**" means the applicable then-current standards for laboratory activities for pharmaceuticals or biologicals, as set forth in the FFDCA and any regulations or guidance documents promulgated thereunder, as amended from time to time, together with, with respect to work performed in a country other than the United States, any similar standards of good laboratory practice as are required by any Regulatory Authority in such country.

1.74"**GMP**" means the applicable then-current standards for conducting Manufacturing activities for pharmaceuticals or biologicals (or active pharmaceutical ingredients) as are required by any applicable Regulatory Authority in the Territory.

1.75 "**Governmental Authority**" means any federal, state, national, provincial or local government, or political subdivision thereof, or any multinational organization or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, or any court or tribunal (or any department, bureau or division thereof, or any governmental arbitrator or arbitral body).

1.76"**Hyslink License Agreement**" means that certain "Technology Exclusive License Agreement" by and between MabCare and Shanghai Huilian Biopharmaceutical Co., Ltd ("**Hyslink**") having an effective date of September 1, 2022, as may be amended as permitted herein [*].

1.77"**Hyslink Licensed Patent**" has the meaning set forth in Section 8.8.

1.78 "**IAS/IFRS**" means International Accounting Standards/International Financial Reporting Standards of the International Accounting Standards Board, consistently applied.

1.79 "**IND**" means an investigational new drug application, clinical trial authorization application ("**CTA**"), or similar application or submission (including any supplements of any of the foregoing) for approval to conduct Clinical Trials of a pharmaceutical or biological product filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority.

1.80 "**Indemnified Party**" has the meaning set forth in Section 10.3.1.

1.81 "**Indemnifying Party**" has the meaning set forth in Section 10.3.1.

1.82 "**Indication**" means any separate and distinct disease or medical condition in humans. [*]

1.83 "**Initial Dose Escalation Study**" means the first portion of a Clinical Trial of a product that is intended to evaluate potential doses of such product by introducing progressively higher doses of such product into small cohorts of patients (or healthy subjects) to assess its safety, metabolism, pharmacokinetic properties, or clinical pharmacology.

1.84 "**Initial Registrational or Randomized Study**" means a Clinical Trial of a product that is intended to (a) obtain sufficient efficacy and safety data in patients via a single-arm or randomized trial with the indication being studied which is confirmed in writing with the relevant Regulatory Authority to support accelerated (including conditional or other analogous) Regulatory Approval for such indication or (b) provide additional efficacy and safety data via a randomized trial to support continued development of the product.

1.85 "**Initiation**" means, with respect to a Clinical Trial, the first dosing of the first patient in such Clinical Trial.

1.86 "**Insolvent Event**" has the meaning set forth in Section 11.4.1.

1.87 "**Joint Foreground Know-How**" means any and all Foreground Know-How that is generated, developed, conceived or reduced to practice jointly by or on behalf of MabCare or any of its Affiliates and Day One or any of its Affiliates.

1.88 "**Joint Foreground Patents**" means any and all Patent Rights that claim Joint Foreground Know-How.

1.89 "**Joint Foreground IP**" means the Joint Foreground Know-How and Joint Foreground Patents.

1.90 "**JSC**" has the meaning set forth in Section 3.1.

1.91 "**Knowledge**" means[*].

1.92 "**Know-How**" means any proprietary or non-public scientific or technical information, inventions, discoveries, results and data of any type whatsoever, in any tangible or intangible form, including inventions, discoveries, databases, safety information, practices, methods, instructions, techniques, processes, drawings, documentation, specifications,

formulations, formulae, knowledge, know-how, trade secrets, skill, experience, test data and other information and technology applicable to formulations, compositions or products or to their manufacture, development, registration, use, marketing or sale or to methods of assaying or testing them, including pharmacological, pharmaceutical, medicinal chemistry, biological, chemical, biochemical, toxicological and clinical test data, physical and analytical, safety, quality control data, manufacturing, and stability data, studies and procedures, and manufacturing process and development information, results and data.

1.93 "**Licensed Compound**" means any ADC Directed To PTK7 Controlled by MabCare or its Affiliates as of the Effective Date or during the Term, including CB-002, but excluding, for clarity, any such ADC in an Acquirer Program of MabCare's Acquirer.

1.94 "**Licensed Product**" means any product containing or comprising a Licensed Compound (alone or in the form of a Combination Product) in all forms, presentations, formulations, methods of administration and dosage forms.

1.95 "**Linker**" means a chemical composition or method for attaching a Payload to an antibody.

1.96 "**Losses**" has the meaning set forth in Section 10.1.

1.97 "**MabCare Development Plan**" has the meaning set forth in Section 4.4.1.

1.98 "**MabCare Foreground Know-How**" means any and all Foreground Know-How generated, developed, conceived or reduced to practice solely by on behalf of MabCare or its Affiliates other than improvements solely with respect to Day One Background Know-How.

1.99 "**MabCare Foreground Patents**" means any and all Patent Rights that claim MabCare Foreground Know-How.

1.100 "**MabCare Indemnitee**" has the meaning set forth in Section 10.1.

1.101 "**MabCare Know-How**" means any and all Know-How Controlled by MabCare or any of its Affiliates as of the Effective Date or during the Term that is necessary or reasonably useful to Develop, Manufacture, Commercialize or otherwise exploit the Licensed Compounds and Licensed Products in accordance with the terms of this Agreement. The MabCare Know-How includes the MabCare Foreground Know-How.

1.102 "**MabCare Manufacturing Agreements**" means the (a) QuaCell Agreement, (b) Technology Development (Payload-Linker GMP Manufacturing) Agreement by and between MabCare and ChemExpress, dated September 21, 2023, and (c) Master Services Agreement by and between MabCare and Intellective Biologics (together with any Work Order), dated June 30, 2023, with the work order dated June 30, 2023.

1.103 "**MabCare Materials**" means the cell line used by MabCare for the Manufacture of CB-002 and listed in Schedule 1.103.

1.104 "**MabCare Patents**" means any and all Patent Rights Controlled by MabCare or

any of its Affiliates as of the Effective Date or during the Term that are necessary to Develop, Manufacture, Commercialize or otherwise exploit the Licensed Compounds and Licensed Products in accordance with the terms of this Agreement. The MabCare Patents include the MabCare Foreground Patents in the Day One Territory. The MabCare Patents existing as of the Effective Date are listed on Schedule 1.104 hereto. During the Term, MabCare will update Schedule 1.104 upon the reasonable request of Day One.

1.105"**MabCare PCT**" has the meaning set forth in Section 8.2.1.

1.106"**MabCare Platform**" means [*].

1.107"**MabCare Technology**" means the MabCare Know-How and MabCare Patents, including any MabCare Know-How within and MabCare Patent Rights Covering the MabCare Materials.

1.108"**MabCare Territory**" means Mainland China, the Hong Kong Special Administrative Region (SAR), the Macau Special Administrative Region (SAR) and Taiwan.

1.109"**Major Markets**" has the meaning set forth in Section 4.3.

1.110"**Manufacture**" means all activities in connection with the manufacture of a compound or product, including the processing, formulating, testing (including quality control, quality assurance and lot release testing), bulk packaging, filling, finishing, packaging, labeling, inspecting, receiving, storage, release, shipping and delivery, sourcing of materials, process qualification, validation and optimization, and stability testing of such compound or product. For the avoidance of doubt, the right to Manufacture a product will include the right to make, have made, use and import such compound or product for the purposes set forth above. "**Manufacturing**" and "**Manufactured**" have a corresponding meaning.

1.111"**Manufacturing Technology Transfer**" has the meaning set forth in Section 5.3.

1.112"**Manufacturing Technology Transfer Budget**" has the meaning set forth in Section 5.3.

1.113"**Manufacturing Technology Transfer Plan**" has the meaning set forth in Section 5.3.

1.114 "**Marketing Authorization Application**" or "**MAA**" means, with respect to a product, a Biologics License Application, as described in the United States Public Health Service Act, or any equivalent thereto in any country outside of the U.S., filed with the applicable Regulatory Approval in support of approval to market such product in the applicable country or jurisdiction, including any amendments and supplements thereto.

1.115"**Material Development Issue**" has the meaning set forth in Section 4.4.1.

1.116[*]

1.117"**Negotiation Period**" has the meaning set forth in Section 2.3.2(b).

1.118"**Net Sales**" means, with respect to a Licensed Product, the gross amount invoiced by Day One, its Affiliates or Sublicensees (each a "**Selling Party**") to Third Parties (including Distributors of Day One, its Affiliates or Sublicensees) for such Licensed Product in the Territory, less (to the extent such deduction is not already reflected in the amount invoiced):

1.118.1[*]

1.118.2[*]

1.118.3[*]

1.118.4[*]

1.118.5[*]

1.118.6[*]

1.118.7[*]

Net Sales shall be determined from [*] Transfers of Licensed Product between or among Day One, its Affiliates and Sublicensees for subsequent resale shall not be included in Net Sales, but the subsequent end sale shall be included in Net Sales. Net Sales shall not include Licensed Product provided for: (a) research and Clinical Trial purposes prior to or in support of Regulatory Approval; (b) compassionate use, named patient sales, patient assistance programs, in each case, that are not intended for general use or sale of such Licensed Product without Regulatory Approval; (c) test marketing programs or other similar programs or studies, or for sample or promotional purposes (provided that the Licensed Product is not otherwise generally available for purchase in the applicable country, and are provided at no cost or below cost); or (d) early access programs that are not intended for general use or sale of such Licensed Product without Regulatory Approval.

If any Licensed Product is sold as part of a Combination Product, then Net Sales for such Licensed Product shall be determined by multiplying the net sales of the Combination Product [*] (the "**Other Product(s)**").

If the weighted average sale price of a Licensed Product when sold separately in finished form can be determined but the weighted average sale price of the Other Product(s) cannot be determined, then Net Sales for such Combination Product shall be calculated by multiplying the net sales of such Combination Product (as calculated in accordance with analogous criteria as set forth above for the "Net Sales" definition) by the fraction A / C where A is the weighted average sale price of such Licensed Product when sold separately in finished form and C is the weighted average sale price of the Combination Product.

If the weighted average sale price of the Other Product(s) can be determined but the weighted average sale price of the Licensed Product when sold separately in finished form cannot be determined, Net Sales for such Combination Product shall be calculated by multiplying the net sales of such Combination Product (as calculated in accordance with analogous criteria as set forth above for the "Net Sales" definition) by the following formula: one (1) minus B / C where B is the

weighted average sale price of the Other Product(s) and C is the weighted average sale price of the Combination Product.

If the weighted average sale price of both a Licensed Product and the Other Product(s) cannot be determined, then Net Sales for such Combination Product shall be mutually agreed by the Parties in good faith, which determination shall reasonably reflect the fair market value of the contribution of such Licensed Product and Other Product(s) in such Combination Product to the total fair market value of such Combination Product.

1.119"**Patent Challenge**" has the meaning set forth in Section 11.5.

1.120[*].

1.121 "**Patent Rights**" means all patents and patent applications (including any certificates of invention, supplementary protection certificates and applications therefor, applications for certificates of invention and priority rights) in any country or other jurisdiction, including all international applications, provisional applications, substitutions, continuations, continuations-in-part, continued prosecution applications, including requests for continued examination, divisional applications and renewals, and all letters, patents or certificates of invention granted thereon, and all reissues, reexaminations, term extensions, term adjustments, term restorations, renewals, substitutions, confirmations, registrations, revalidations, revisions and additions of or to any of the foregoing, in each case, in any country or other jurisdiction.

1.122"**Patent Term Extension**" has the meaning set forth in Section 8.3.

1.123"**Payload**" means a molecule engineered or intended to or that does kill or otherwise modulate a tumor cell for therapeutic benefit.

1.124"**Permitted Purpose**" has the meaning set forth in Section 5.4.

1.125"**Person**" means any individual, corporation, company, partnership, association, joint-stock company, trust, unincorporated organization or governmental or political subdivision thereof.

1.126"**Pharmacovigilance Agreement**" has the meaning set forth in Section 4.6.

1.127 "**Pricing and Reimbursement Approval**" means, in any country where a Governmental Authority, in connection with Regulatory Approval, authorizes reimbursement for, or approves or determines pricing for, pharmaceutical products, receipt (or, if required to make such authorization, approval or determination effective, publication) of such reimbursement authorization or pricing approval or determination (as the case may be).

1.128"**Personal Data**" has the meaning set forth in Section 9.3.1.

1.129"**Product Trademarks**" has the meaning set forth in Section 8.10.

1.130"**Proposed Publication**" has the meaning set forth in Section 7.6.

1.131"**Prosecute and Maintain**" means activities directed to: (a) preparing, filing and prosecuting Patent Rights; (b) managing any interference, opposition, re-issue, reexamination, supplemental examination, invalidation proceedings (including *inter partes* or post-grant review proceedings), revocation, nullification or cancellation proceeding relating to the foregoing; and (c) settling any interference, opposition, reexamination, invalidation, revocation, nullification or cancellation proceeding, but excluding the defense of challenges to Patent Rights as a declaratory judgment action or as a counterclaim in an infringement proceeding.

1.132"**QuaCell Agreement**" means the Non-Exclusive Material License Agreement on QuaCell CHO-K1Q Cell Line, by and between QuaCell Biotechnology, Co. Ltd ("**QuaCell**") and MabCare, dated March 1, 2024.

1.133"**Qualified Sublicensee**" means[*]

1.134"**Regulatory Approval**" means, with respect to a given product and a given country or other jurisdiction, any and all approvals (including MAA approval or accelerated approval), licenses, registrations, or authorizations of any Regulatory Authority necessary to Commercialize such product in such country or other jurisdiction, including, where necessary for Commercialization, Pricing and Reimbursement Approval(s). For clarity, Pricing and Reimbursement Approval shall not be necessary in the United States to achieve "Regulatory Approval" for purposes of Section 6.2.

1.135 "**Regulatory Authority**" means any applicable Governmental Authority with authority over the distribution, importation, exportation, manufacture, production, use, storage, transport, clinical testing or sale of a pharmaceutical or biological product, including any Governmental Authority having the authority to grant Regulatory Approval or Pricing and Reimbursement Approval.

1.136 "**Regulatory Exclusivity"** means, with respect to a Licensed Product and a country, a period of exclusivity (other than Patent Rights exclusivity) granted or afforded by Applicable Laws or by a Regulatory Authority in such country that prevents the Regulatory Approval or marketing of any Biosimilar Product of such Licensed Product in such country.

1.137"**Regulatory Materials**" means all (a) applications (including all INDs, MAAs and applications for Pricing and Reimbursement Approval), registrations, licenses, authorizations and approvals (including Regulatory Approvals and Pricing and Reimbursement Approvals), (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all adverse event files and complaint files, (c) supplements or changes to any of the foregoing, and (d) clinical and other data, including Clinical Trial data, contained or relied upon in any of the foregoing.

1.138"**Regulatory Submissions**" means all Regulatory Materials submitted to a Regulatory Authority in support of the Development, Manufacture or Commercialization of a product.

1.139"**Remedial Action**" has the meaning set forth in Section 4.7.

1.140"**Required Filings**" has the meaning set forth in Section 12.19.

1.141"**Reversion License**" has the meaning set forth in Section 11.9.2.

1.142"**Reversion Product**" has the meaning set forth in Section 11.9.2.

1.143"**Review Period**" has the meaning set forth in Section 7.6.

1.144"**ROFN Notice**" has the meaning set forth in Section 2.3.2(b).

1.145"ROFN Decline" has the meaning set forth in Section 2.3.2(b).

1.146"**Royalty Term**" means, on a Licensed Product-by-Licensed Product and country-by-country basis, the period beginning on the date of the First Commercial Sale of such Licensed Product in such country and ending upon the date of the latest of (a) the expiration of the last Valid Claim of the MabCare Patents or Joint Foreground Patents that Cover (i) the composition of matter of such Licensed Product in such country, or (ii) method of use of such Licensed Product for an Indication set forth on the approved product labeling for such Licensed Product in such country, (b) the tenth (10th) anniversary of the date of the First Commercial Sale of such Licensed Product in such country, and (c) termination or expiration of Regulatory Exclusivity for such Licensed Product in such country.

1.147"**Sales Milestone Event**" has the meaning set forth in Section 6.3.

1.148"**Sales Milestone Payment**" has the meaning set forth in Section 6.3.

1.149"**Securities Regulations**" has the meaning set forth in Section 7.5.2.

1.150"**Securities Regulator**" has the meaning set forth in Section 7.5.2.

1.151"**Segregate**" means, [*]

1.152"**SIAC**" has the meaning set forth in Section 12.5.2.

1.153"**Simon Two-Stage Design Dose Expansion Study**" means a portion of a Clinical Trial of a product that (a) introduces into patients solely the recommended dose(s) of such product, as determined by a recommended dose study of such product, and (b) employs at least two (2) concurrently accruing patient cohorts, where each cohort is intended to assess a different aspect of such product such as its safety, metabolism, pharmacokinetic properties, clinical pharmacology, or antitumor activity.

1.154"**Skipped Development/Commercial Milestone**" has the meaning set forth in Section 6.2.

1.155"**Specified Patent Right**" [*]

1.156"**Specific Patent Right Costs**" [*]

1.157"**Specific Patent Right Payments**" [*]

1.158"**Subcontractor**" has the meaning set forth in Section 2.4.

1.159"**Sublicense**" means [*].

1.160"**Sublicensee**" has the meaning set forth in Section 2.3.1.

1.161"**Sublicensing Income**" means [*].

1.162"**Substitution Clinical Trial**" has the meaning set forth in Section 6.2.

1.163"**Technology Transfer**" has the meaning set forth in Section 4.1.1.

1.164"**Term**" has the meaning set forth in Section 11.1.

1.165 "**Territory**" means, with respect to Day One, the Day One Territory, and with respect to MabCare, the MabCare Territory.

1.166"**Third Party**" means any Person, other than a Party or an Affiliate of a Party.

1.167"**Third Party Claim**" has the meaning set forth in Section 10.1.

1.168"**Third Party Infringement Claim**" has the meaning set forth in Section 8.7.1.

1.169"**Third Party Payments**" has the meaning set forth in Section 6.4.2.

1.170"**Transferred Regulatory Materials**" has the meaning set forth in Section 4.1.2.

1.171"**United States**" or "**U.S.**" means the United States of America and its territories and possessions.

1.172"**Upfront Fee**" has the meaning set forth in Section 6.1.

1.173"**U.S. Bankruptcy Code**" has the meaning set forth in Section 11.4.2.

1.174"**USD**" or "**Dollars**" means United States dollars.

1.175 "**Valid Claim**" means a claim (a) in an issued and unexpired Patent that has not been held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction, and which has not been admitted as invalid or unenforceable through abandonment, reissue, disclaimer or otherwise, such holding or decision being final and unappealable or unappealed within the time allowed for appeal; or (b) in a pending Patent application *provided, however*, that a pending claim of a patent application shall cease to be a Valid Claim if such pending claim does not issue within seven (7) years after the filing date of the patent application from which it arose, unless and until such pending claim has issued thereafter, and satisfies subsection (a) of this definition.

1.176"**VAT**" has the meaning set forth in Section 6.11.3.

1.177"**Withholding Taxes**" has the meaning set forth in Section 6.11.1.

ARTICLE 2
LICENSE

2.1Exclusive License to Day One. Subject to the terms and conditions of this Agreement, MabCare, on behalf of itself and its Affiliates, hereby grants to Day One an exclusive (even as to MabCare and its Affiliates), non-transferable (except in accordance with Section 12.1), royalty-bearing license, with the right to grant sublicenses through multiple tiers in accordance with Section 2.3.1, under the MabCare Technology and MabCare's interest in the Joint Foreground IP to make, have made, use, import, offer for sale, sell, Develop, Manufacture, Commercialize and otherwise exploit Licensed Compounds and Licensed Products in the Field in the Day One Territory in accordance with the terms of this Agreement. Notwithstanding any other provision of this Agreement, [*].

2.2License to MabCare. Subject to the terms and conditions of this Agreement, Day One, on behalf of itself and its Affiliates, hereby grants to MabCare an exclusive (even as to Day One and its Affiliates), non-transferable (except in accordance with Section 12.1), royalty-free license, with the right to grant sublicenses (solely in accordance with Section 2.3.2), under the Day One Technology and Day One's interest in the Joint Foreground IP, to make, have made, use, import, offer for sale, sell, Develop, Manufacture, Commercialize and otherwise exploit CB-002 and CB-002 Products in the Field in the MabCare Territory in accordance with the terms of this Agreement. For the avoidance of doubt, [*]. Notwithstanding any other provision of this Agreement, [*].

2.3Right to Sublicense.

2.3.1**Day One**. Day One shall have the right to grant sublicenses under the rights granted to it in Section 2.1 through multiple tiers, without MabCare's prior consent, to its Affiliates and Third Parties (each such Third Party a "**Sublicensee**"). All such Sublicensees shall be subject to a written agreement [*]. Day One shall remain responsible and liable to MabCare for the performance of its Sublicensees to the same extent as if such activities were conducted by Day One. Day One shall provide a copy of each sublicense agreement with a Sublicensee to MabCare reasonably promptly after the execution of such sublicense agreement, provided that such sublicense agreement may be redacted to exclude any confidential or proprietary information of Day One, its Affiliates or the Sublicensee contained therein that is not necessary to determine compliance with this Section 2.3.1.

2.3.2**MabCare**.

(a) **Right to License and Sublicense**. MabCare and its Affiliates shall have the right to grant [*] under the following conditions:

(x) [*]

(y) [*]

All such (sub)licensees shall be subject to a written agreement consistent with the applicable terms and conditions of this Agreement, including [*]. MabCare shall remain responsible and liable to Day One for the performance of MabCare's obligations under this Agreement by its sublicensees or licensees who have been granted rights to Develop, Manufacture or Commercialize Licensed Compounds and Licensed Products. MabCare shall provide a copy of each (sub)license agreement with a (sub)licensee to Day One reasonably promptly after the execution of such (sub)license agreement, provided that such (sub)license agreement may be redacted to exclude any confidential or proprietary information of MabCare, its Affiliates or the (sub)licensee contained therein that is not necessary to determine compliance with this Section 2.3.2.

(b) **Right of First Negotiation**. [*]

2.4 Right to Subcontract. Each Party shall have the right to subcontract the performance of any of its obligations under this Agreement to one or more Third Party subcontractors engaged for the purpose of such Party's Development, Manufacture and Commercialization of Licensed Compounds and Licensed Products as set forth herein (each such Third Party a "**Subcontractor**"). All such Subcontractors shall be subject to a written agreement that is consistent with the applicable terms and conditions of this Agreement. A Party shall remain responsible and liable to the other Party for the performance of its Subcontractors to the same extent as if such activities were conducted by such Party. For clarity, entities such as contract research organizations, CMOs, Clinical Trial sites, Distributors and contract sales organizations shall be considered Subcontractors under this Section 2.4 and not (sub)licensees for purposes of Section 2.3.

2.5 Retained Rights. Notwithstanding the exclusive nature of the license granted to Day One in Section 2.1 MabCare retains the rights to practice the MabCare Technology (a) to perform its obligations under this Agreement, and (b) outside the scope of the exclusive license granted in Section 2.1. Notwithstanding the exclusive nature of the license granted to MabCare in Section 2.2, Day One retains the rights to practice the Day One Technology (a) to perform its obligations under this Agreement, and (b) outside the scope of the exclusive license granted in Section 2.2.

2.6 No Implied Licenses. Except as expressly set forth in this Agreement, neither Party nor its Affiliates, by virtue of this Agreement, shall acquire any license or other interest, by implication or otherwise, in or to any Know-How, Patent Rights, or other intellectual property rights owned or controlled by the other Party or its Affiliates.

2.7 Third Party Licenses.

2.7.1 [*]

2.7.2 [*]

2.7.3 Notwithstanding Section 2.7.1 and Section 2.7.2:

[*]

2.8Hyslink License Agreement. Day One acknowledges and agrees that [*].

2.9Exclusivity; Change of Control.

2.9.1**Competing Products**. [*], neither Party will, and will ensure that its Affiliates do not, (a) either alone or with a Third Party, make, have made, use, sell, offer for sale, import or otherwise Develop, Manufacture, Commercialize or exploit any Competing Product or (b) license, authorize, appoint, advise, assist or otherwise enable any Third Party to Develop, Manufacture, Commercialize or exploit any Competing Product, in each case ((a) or (b)), anywhere in the world.

2.9.2**Exceptions.** Notwithstanding Section 2.9.1, if a Party or any of its Affiliates (a) undergoes a Change of Control and, on the date of the closing of such Change of Control or thereafter, the Acquirer has a product or program that would be in violation of Section 2.9.1 (each an "**Acquirer Program**"), or (b) acquires a Third Party by merger, purchase of assets, stock acquisition or otherwise, and on the date of the closing of such transaction, such Third Party has a product or program that, upon the closing of such transaction, would be in violation of Section 2.9.1 ("**Acquired Program**"), then, the following shall apply: [*]

ARTICLE 3
GOVERNANCE

3.1 Joint Steering Committee. Promptly after the Effective Date, the Parties shall establish a Joint Steering Committee (the "**JSC**") to provide a forum for the coordination, communication, and oversight of Development and Manufacturing activities with respect to Licensed Compounds and Licensed Products. The JSC shall carry out the following specific responsibilities:

3.1.1 review and discuss the status, progress and results of Development activities conducted by either Party in their respective Territory;

3.1.2 review and discuss any proposed amendments or revisions to Day One's Development Plan or MabCare's Development Plan;

3.1.3coordinate MabCare's Development activities with Day One's Development activities;

3.1.4oversee the Technology Transfer;

3.1.5oversee the sharing of Data;

3.1.6review and advise on amendments to the Manufacturing Technology Transfer Plan and Manufacturing Technology Transfer Budget;

3.1.7oversee the conduct of the Manufacturing Technology Transfer Plan;

3.1.8 establish procedures regarding the collection, sharing, and reporting of Adverse Event information related to Licensed Compounds and Licensed Products consistent with

the Pharmacovigilance Agreement to be entered into in accordance with Section 4.6;

3.1.9facilitate communications regarding any Commercialization activities in each Party's Territory; and

3.1.10perform such other functions as expressly set forth in this Agreement.

3.2Composition and Meetings.

3.2.1**Composition**. The JSC shall be composed of [*] of each of Day One and MabCare, and each Party shall notify the other Party of its initial JSC representatives within thirty (30) days after the Effective Date. Each Party shall [*]. Each Party may change its JSC representatives from time to time in its sole discretion, effective upon notice to the other Party of such change. Each Party's JSC representatives shall be employees of such Party with appropriate experience and authority within such Party's organization. A reasonable number of representatives of each Party who are not JSC members may attend meetings of the JSC; provided, however, that if either Party intends to have any Third Party (including any consultant) attend such a meeting, such Party shall provide prior written notice to the other Party, shall obtain approval from such other Party for such Third Party to attend (not to unreasonably withheld, conditioned or delayed), and shall ensure that such Third Party is bound by confidentiality and non-use obligations consistent with the terms of this Agreement. The JSC may establish joint teams (on an "as-needed" basis to oversee particular projects or activities, which delegations shall be reflected in the minutes of the meetings of the JSC) and disband such joint teams. Each such joint team shall consist of the same number of representatives from each Party, which number shall be mutually agreed by the Parties. Each Party shall be free to change its joint team representatives on written notice to the other Party or to send a substitute representative to any joint team meeting from time to time on a reasonable basis. Each joint team shall report to the JSC and shall have no decision-making authority.

3.2.2**Meetings**. The JSC will hold a meeting [*]. Such meetings may be in person, via videoconference, or via teleconference. The location of in-person meetings will be determined by the Parties. [*] prior to a JSC meeting, the chairpersons will distribute to the JSC members the agenda items for discussion at such meeting, together with appropriate information related thereto. Reasonably detailed written minutes will be kept of all JSC meetings. Meeting minutes will be prepared by [*]. Minutes will be deemed approved unless [*].

3.3Decision-Making Authority. Subject to the terms and conditions of this Agreement, each Party shall have the sole decision-making authority with respect to the Development, Manufacturing and Commercialization activities solely with respect to its own Territory, and the JSC shall be a forum for communication, coordination and advisory purposes only, provided however, [*]:

3.3.1[*]

3.4Discontinuation. If at any point during the Term the JSC does not have any ongoing responsibilities, the Parties may mutually agree to disband the JSC.

3.5 Limitations on Authority. The JSC shall only have the powers expressly assigned to it in this Article 3 and elsewhere in this Agreement and shall not have the authority to (a) modify or amend the terms and conditions of this Agreement, (b) waive either Party's compliance with, or determine that either Party has or has not fulfilled, the terms and conditions of this Agreement, or (c) determine any issue in a manner that would conflict with, expand, or reduce the express terms and conditions of this Agreement.

ARTICLE 4
DEVELOPMENT AND COMMERCIALIZATION

4.1 Technology Transfer.

4.1.1 **Technology Transfer**. [*] MabCare shall disclose and make available (or cause to be disclosed or made available) to Day One all MabCare Know-How in the possession or control of MabCare or its Affiliates, including (a) all preclinical and clinical data for CB-002, (b) all Regulatory Materials and Regulatory Submissions related to or for CB-002, including all Know-How used to support the IND submitted to the FDA for CB-002, and (c) all Know-How and information related to, or reasonably necessary to support, the continued Development and Commercialization of CB-002 or other Licensed Compounds by Day One (the "**Technology Transfer**"). To the extent any such MabCare Know-How resides with a Third Party [*]. For clarity, the Technology Transfer will not include the Manufacturing Technology Transfer, which is governed by Section 5.3. MabCare may make such MabCare Know-How available by [*]. All MabCare Know-How will be provided in a format [*]. If after the Effective Date, MabCare or Day One identify any MabCare Know-How that should have been included in the Technology Transfer but was inadvertently omitted, MabCare shall promptly disclose and make available to Licensee such Know-How in a manner consistent with the preceding sentence. During and following the Technology Transfer, at the reasonable request of Day One, MabCare shall cause its (and its Affiliates') scientific and technical personnel available to answer reasonable technical or scientific questions regarding the Licensed Compounds, Licensed Products or content of the Technology Transfer. Unless otherwise expressly provided herein, [*]

4.1.2 **IND Transfer**. [*] MabCare shall transfer and assign to Day One or its designee the Regulatory Materials and Regulatory Submissions for Licensed Compounds and Licensed Products (including CB-002) in the Day One Territory and listed on Schedule 4.1.2, including, the U.S. IND for CB-002 (the "**Transferred Regulatory Materials**"). Without limiting the foregoing, MabCare shall initiate the transfer and assignment of such Transferred Regulatory Materials [*]. Until such transfer and assignment is complete, MabCare shall maintain the Transferred Regulatory Materials in good standing. In the event that [*].

4.1.3 **Existing Inventory**. [*] MabCare will transfer the existing supply of Licensed Product as set forth in Schedule 4.1.3 (the "**Existing Inventory**") to Day One or its designee, which transfer shall be completed [*] MabCare represents and warrants to Day One (as of the Effective Date and as of the date of delivery of the Existing Inventory to Day One) that [*]. MabCare shall provide Day One with an invoice for the Existing Inventory upon delivery and Day One shall pay the invoiced amount to MabCare [*]. MabCare shall continue to support [*]. Notwithstanding anything to the contrary herein, Day One acknowledges and agrees that the Existing Inventory has been stored at MabCare's existing CMO as described in Schedule 4.1.3,

and [*].

4.1.4 **MabCare Vendors and Subcontractors**. Upon Day One's request, MabCare will (a) assign to Day One or its designee (to the extent assignable and without penalty to MabCare or its Affiliate) any of MabCare's or its Affiliates' agreements with Third Party vendors and subcontractors that are related solely and exclusively to the Development of Licensed Compounds or Licensed Products or, to the extent any such Third Party agreement or arrangement is not assignable to Day One or its designee, reasonably cooperate with Day One to arrange to continue to provide such services for a reasonable time, or (b) introduce Day One to any Third Party vendor or subcontractor performing Development activities for MabCare or its Affiliates in connection with the Licensed Compounds or Licensed Products and reasonably cooperate with Day One's efforts to enter into an agreement directly with such vendor or subcontractor, in each case (a) and (b), solely with respect to the Day One Territory.

4.2Development and Commercialization Responsibility.

4.2.1 **Day One Territory**. Except as expressly set forth herein, as between the Parties, Day One shall have the sole responsibility and authority, at its sole cost and expense, for the Development and Commercialization of Licensed Compounds and Licensed Products in the Field in the Day One Territory. Without limiting the foregoing, as between the Parties, Day One shall (a) have the sole authority and discretion to prepare, file, prosecute and maintain any and all Regulatory Submissions (including any Pricing and Reimbursement Approvals), and to communicate and otherwise interact with all Regulatory Authorities, with respect to the Licensed Compounds and Licensed Products in the Day One Territory, and (b) own all Regulatory Submissions, Regulatory Approvals, and Pricing and Reimbursement Approvals for the Licensed Compounds and Licensed Products in the Day One Territory.

4.2.2 **MabCare Territory**. Except as expressly set forth herein, as between the Parties, MabCare shall have the sole responsibility and authority, at its sole cost and expense, for the Development and Commercialization of Licensed Compounds and Licensed Products in the Field in the MabCare Territory. Without limiting the foregoing, as between the Parties, MabCare shall (a) have the sole authority and discretion to prepare, file, prosecute and maintain any and all Regulatory Submissions (including any Pricing and Reimbursement Approvals), and to communicate and otherwise interact with all Regulatory Authorities, with respect to the Licensed Compounds and Licensed Products in the MabCare Territory, and (b) own all Regulatory Submissions, Regulatory Approvals, and Pricing and Reimbursement Approvals for the Licensed Compounds and Licensed Products in the MabCare Territory.

4.3Day One Diligence. Day One shall (itself or through its Affiliates or Sublicensees) use Commercially Reasonable Efforts to [*] (collectively, "**Major Markets**").

4.4Development Coordination.

4.4.1 **Development Plan.** The Parties intend to coordinate their Development activities in the Territory as set forth in this Section 4.4. The initial development plan for the Development of the Licensed Product in the Day One Territory is attached hereto as Schedule 4.4.1 (such plan and any updates thereto, the "**Day One Development Plan**"). MabCare shall

provide an initial development plan[*] (such plan and any updates thereto, the "**MabCare Development Plan**", and each Day One Development Plan or MabCare Development Plan, a "**Development Plan**"). A Party's Development Plan shall include [*], and timelines for achievement thereof, in the corresponding Territory. Each Development Plan (or any update thereto) shall be [*]. Day One shall have the right to [*] (each, a "**Material Development Issue**"), and the Parties shall resolve such issue via the JSC in accordance with Section 3.3. Each Party shall update its Development Plan [*] and provide such updated Development Plan to the JSC for review and discussion. Each Party shall not conduct any Development of the Licensed Compounds or Licensed Products [*].

4.4.2 **Development Reports**. Each Party shall provide to the other Party, via the JSC, [*]. All such Development reports shall be the Confidential Information of the providing Party.

4.4.3 **Data Sharing**. The Parties will mutually agree upon a procedure for the exchange of Data ([*]). The JSC shall oversee the sharing of Data between the Parties. Each Party will take such actions as may be reasonably requested by the other Party to give effect to the intent of this section. For clarity, [*].

4.4.4 **Right of Access and Reference**. Each Party hereby grants to the other Party a right of reference to all Regulatory Materials and Regulatory Submissions submitted by such Party, its Affiliates or (sub)licensees in its respective Territory for the Licensed Compounds and Licensed Products (including, for clarity, the right of reference to Transferred Regulatory Materials by MabCare, its Affiliates or (sub)licensees) solely for the purpose of such other Party, its Affiliates or (sub)licensees obtaining or maintaining Regulatory Approvals in its respective Territory for the Licensed Compounds and Licensed Products. Each Party will take such actions as may be reasonably requested by the other Party to give effect to the intent of this section, including providing a cross-reference letter or similar communication to the applicable Regulatory Authority to effectuate such right of access and reference.

4.4.5 **Development Records.** Each Party shall maintain complete, current and accurate records of all Development activities conducted by or on behalf of it, its Affiliates or its (sub)licensees pursuant to this Agreement and all data and other information resulting from such activities, in each case in accordance with all Applicable Law. Such records shall (i) be maintained [*].

4.4.6 **Audit**. Day One or its representatives may, for actual cause or based upon a reasonable belief of non-compliance with MabCare's Development Plan, at reasonable times (which audit shall not be more than once in every twelve (12) month period, unless otherwise for actual cause) and upon reasonable notice, perform audits of MabCare's or its Affiliates' or (sub)licensees' Development activities with respect to the Licensed Compounds and Licensed Products in the MabCare Territory, and any Clinical Trial sites engaged, or other facilities used, by MabCare or its Affiliates, or (sub)licensees or vendors to conduct the applicable Development Plan, subject to any confidentiality obligations and safety procedures as may be reasonably required by MabCare's or its Affiliates, (sub)licensees or sites and other facilities. [*] Day One will provide MabCare with a written summary of its findings in English, including any deficiencies or other areas of remediation that Day One reasonably identifies during such audit, and the Parties

shall promptly meet to discuss such findings and proposed remedial actions. If the Parties agree on a proposed remedial action, then MabCare [*].

4.5 Communications with Regulatory Authorities. Except as set forth herein or as otherwise agreed by the Parties, (i) neither Party shall communicate with any Regulatory Authority having jurisdiction outside of its respective Territory with respect to the Licensed Compounds or Licensed Products, unless required by such Regulatory Authority, in which case [*], and (ii) neither Party shall submit any Regulatory Materials nor seek Regulatory Approval for the Licensed Product in the other Party's respective Territory.

4.6 Adverse Events Reporting. Reasonably promptly after the Effective Date (or at such other time as agreed upon by the Parties), the Parties (or their respective Affiliates) shall initiate negotiations to enter into a pharmacovigilance agreement for the Licensed Products (such written agreement, the "**Pharmacovigilance Agreement**") for exchanging adverse event and other safety information worldwide with respect thereto. In the event of any inconsistency between the terms of this Agreement and the Pharmacovigilance Agreement, the terms of this Agreement shall prevail and govern, except to the extent such conflicting terms relating directly to the pharmacovigilance responsibilities of the Parties (including the exchange of safety data), in which case the terms of the Pharmacovigilance Agreement shall prevail and govern. The Pharmacovigilance Agreement shall provide for [*]. The Pharmacovigilance Agreement shall ensure that adverse event and other safety information is exchanged according to a schedule that will permit each Party to comply with Applicable Law, including any local regulatory requirements.

4.7 Remedial Actions. Each Party will notify the other Party immediately, and promptly confirm such notice in writing, if it obtains information (including notice by a Regulatory Authority) indicating that any Licensed Product may be subject to any recall, corrective or similar regulatory action by virtue of Applicable Law (each a "**Remedial Action**"). Each Party shall have the right to determine to conduct a Remedial Action in its respective Territory, provided [*].

4.8 Regulatory Agreement. At the request of either Party and if required by Applicable Law, or otherwise mutually agreed to by the Parties, the Parties shall negotiate in good faith and enter into a regulatory agreement setting forth additional details with respect to regulatory matters related to the Licensed Product for the Day One Territory and the MabCare Territory.

4.9 No Diversion. Each Party hereby covenants and agrees that, to the extent not prohibited by Applicable Laws, it shall not, and shall ensure that its Affiliates, distributors, and (sub)licensees do not, knowingly promote, market, distribute for sale, import for sale, sell or have sold a Licensed Product in the other Party's respective Territory. With respect to any country in the other Party's respective Territory, a Party shall not, and shall ensure that its Affiliates, distributors, and (sub)licensees do not: (a) knowingly engage in any advertising or promotional activities relating to a Licensed Product that are directed primarily to customers or other purchaser or users of the Licensed Product located in such countries in the other Party's respective Territory, (b) actively solicit orders for the Licensed Product from any prospective purchaser located in such countries in the other Party's respective Territory, or (c) knowingly sell or distribute the Licensed Product to any person in such Party's respective Territory who intends to sell (or has in the past sold in violation of this clause (c)) the Licensed Product in such countries in the other Party's

respective Territory. If either Party receives any commercial order for the Licensed Product from a prospective purchaser reasonably believed to be located in a country in the other Party's respective Territory or for use of the Licensed Product in the other Party's respective Territory, such Party shall immediately refer that order to the other Party and such Party shall not accept any such orders. Each Party shall not deliver (or tender) for sale (or cause to be delivered (or tendered) for sale) the Licensed Product into a country in the other Party's respective Territory.

ARTICLE 5
MANUFACTURING AND SUPPLY

5.1 Responsibility. Subject to Section 5.2 and Section 5.3, Day One shall have the right to Manufacture, itself or through one or more Third Parties, the Licensed Compounds and Licensed Products for use in the Day One Territory. MabCare shall have the right to Manufacture, itself or through one or more Third Parties, the Licensed Compounds and Licensed Products for use in the MabCare Territory. During the Term, the Parties may coordinate on the Manufacture of Licensed Compounds and Licensed Products for the Territory. Subject to the terms and conditions of this Agreement[*].

5.2 Clinical Supply. Upon Day One's request, the Parties shall negotiate in good faith and enter into a written agreement consistent with the terms set forth on Schedule 5.2 for MabCare to supply (or have its CMO to supply) Day One quantities of the Licensed Product for Day One's clinical Development activities in the Day One Territory (together with a related quality agreement, the "**Clinical Supply Agreement**"). For clarity, unless otherwise mutually agreed by the Parties in writing, following the completion of Manufacturing Technology Transfer, MabCare [*].

5.3 Manufacturing Technology Transfer. [*] the Parties shall promptly prepare a plan and budget for MabCare to promptly and efficiently transfer to Day One or its designee (including one or more Third Party CMOs selected by Day One) all Manufacturing-related MabCare Know-How and materials, including all CMC documentation and data and processes, to enable the Manufacture of the Licensed Products by or for Day One (such plan and budget the "**Manufacturing Technology Transfer Plan**" and "**Manufacturing Technology Transfer Budget**", respectively, and such transfer the "**Manufacturing Technology Transfer**"). The Parties will conduct the Manufacturing Technology Transfer in accordance with the Manufacturing Technology Transfer Plan and Manufacturing Technology Transfer Budget, [*]. Any changes to the Manufacturing Technology Transfer Plan (and corresponding amendments to the Manufacturing Technology Transfer Budget) must be mutually agreed to by the Parties in writing, provided that [*]. In addition, upon Day One's request, MabCare will (a) assign to Day One or its designee (to the extent assignable) any of MabCare's or its Affiliates' agreements with a Third Party CMO that are related solely and exclusively to the Licensed Compounds or Licensed Products in the Day One Territory or, to the extent any such Third Party agreement is not assignable to Day One or its designee, reasonably cooperate with Day One to arrange for such CMO to continue to provide the relevant services for a reasonable time, or (b) introduce Day One to any Third Party CMO performing Manufacturing activities for MabCare or its Affiliates in connection with the Licensed Compounds or Licensed Products and reasonably cooperate with Day One's efforts to enter into an agreement directly with such CMO.

5.4Transfer, Use and Return of MabCare Materials. The Parties acknowledge that, the [*]. At Day One's request and costs after the Effective Date, MabCare will use reasonable efforts to amend [*], or facilitate Day One to enter into a separate agreement directly with [*] for the use of the MabCare Material by Day One to Manufacture (or have Manufactured) the Licensed Compound, and a separate agreement directly with [*] for the use of cell cytotoxicity assays, (such amended [*], or consent or separate agreements (whether entered into by Day One with the facilitation of MabCare or not), collectively, the "**Cell Line Agreements**"). In connection with the Manufacturing Technology Transfer, and subject to the Cell Line Agreements, MabCare shall transfer to Day One MabCare Materials in quantities set forth on Schedule 1.102 for Day One to perform Manufacturing activities in accordance with the Manufacturing Technology Transfer Plan and to perform the cell cytotoxicity assay, as applicable, and thereafter Manufacture the Licensed Compounds and Licensed Products in support of its or its Affiliates' and Sublicensees' Development, Commercialization or other exploitation of the Licensed Compounds and Licensed Products in the Field in Day One Territory in accordance with the terms of this Agreement and the Cell Line Agreements (the "**Permitted Purposes**"). Day One shall only use the MabCare Materials for the Permitted Purposes and for no other purpose. Day One shall use all MabCare Materials in compliance with Applicable Law. Except as expressly set forth in this Agreement or the Cell Line Agreements, Day One shall not [*].

5.5Assistance by MabCare Personnel. Following completion of the Manufacturing Technology Transfer, MabCare shall make available to Day One or its designees (or cause to be made available) technical or scientific personnel of MabCare or its Affiliates as may reasonably be requested by Day One to assist Day One in connection with understanding the content, or implementing or using the content, of the Manufacturing Technology Transfer, and Day One shall reimburse MabCare [*] MabCare shall use reasonable efforts to facilitate the cooperation of any MabCare CMO or other MabCare vendor or subcontractor in connection with providing such assistance, at Day One's cost.

ARTICLE 6
PAYMENTS

6.1Upfront Fee. As partial consideration for the license and other rights granted by MabCare to Day One herein, Day One shall pay to MabCare a one-time, non-refundable, non-creditable upfront fee of fifty-five million Dollars ($55,000,000) within fifteen (15) Business Days of Day One's receipt of an invoice therefor from MabCare(such fee, the "**Upfront Fee**").

6.2Development Milestones. Upon the first achievement by Day One, its Affiliate or Sublicensee of a development or commercial milestone event set forth in the table below (each a "**Development/Commercial Milestone Event**"), Day One shall make the corresponding one-time, non-refundable, non-creditable payment (each a "**Development/Commercial Milestone Payment**") to MabCare in accordance with Section 6.6.1.

#	Development/Commercial Milestone Event	Development/Commercial Milestone Payment (USD)
1	[*]	[*]
2	[*]	[*]
3	[*]	[*]

4	[*]	[*]
5	[*]	[*]
6	[*]	[*]
7	[*]	[*]
8	[*]	[*]
9	[*]	[*]
10	[*]	[*]
11	[*]	[*]
12	[*]	[*]
13	[*]	[*]
14	[*]	[*]
15	[*]	[*]
16	[*]	[*]
17	[*]	[*]
	[*]	**[*]**

[*]

If, upon achievement (or deemed achievement) of a Development/Commercial Milestone Event as set forth in the second column of the table below (each, an "**Achieved Development/Commercial Milestone Event**"), the corresponding Skipped Development/Commercial Milestone Event as set forth in the first column in table below has not yet been achieved, become due or been paid, then such Skipped Development/Commercial Milestone Event shall be deemed achieved and the Development/Commercial Milestone Payment corresponding to such Skipped Development/Commercial Milestone Event shall become due and payable concurrently with the Development/Commercial Milestone Payment corresponding to the applicable Achieved Development/Commercial Milestone.

Skipped Development/Commercial Milestone Event	**Achieved Development/Commercial Milestone Event**
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]

In addition, the Parties agree that, the Day One Development Plan [*]. If Day One amends the Day One Development Plan to conduct, or if its Affiliate or Sublicensee conducts a Clinical Trial, in each case, that is not a [*] (each, as applicable, a "**Substitution Clinical Trial**"), then Development/Commercial Milestone Event [*]. For clarity, a [*] shall not be considered a Substitution Clinical Trial.

6.3Sales Milestones. Upon the first achievement of each sales-based milestone event set forth in the table below (each a "**Sales Milestone Event**"), Day One shall make the corresponding one-time, non-refundable, non-creditable payment (each a "**Sales Milestone Payment**") to MabCare in accordance with Section 6.6.2.

Sales Milestone Event	Sales Milestone Payment (USD)
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	**[*]**

[*]

6.4Royalty Payments.

6.4.1 **Royalty Payments for Licensed Products**. Subject to the remainder of this Section 6.4, on a Licensed Product-by-Licensed Product basis, during the Royalty Term for such Licensed Product, Day One shall pay MabCare royalties on aggregate annual Net Sales of such Licensed Product in the Day One Territory as follows:

Aggregate Annual Net Sales in the Day One Territory per Licensed Product	Royalty Rate
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]

Following the expiration of the Royalty Term for a Licensed Product in a given country, Net Sales of such Licensed Product in such country will be excluded from Net Sales for purposes of determining the royalties due hereunder (including that Net Sales of such Licensed Product in such country shall not be considered when determining the allocation of Net Sales among the royalty tiers set forth above) and Sales Milestones Events. Such royalty payments, and associated reports, shall be made in accordance with Section 6.6.2.

6.4.2**Royalty Reductions**.

(a)**No Valid Claim**. On a Licensed Product-by-Licensed Product and country-by-country basis in the Day One Territory, if at any time during the Royalty Term for such Licensed Product there is no Valid Claim of any MabCare Patent or Joint Foreground Patent that Covers (i) the composition of matter of the Licensed Compound of such Licensed Product in such country, or (ii) method of use of such Licensed Product for an Indication set forth on the approved product labeling for such Licensed Product in such country, then the royalty rates set forth in Section 6.4.1 shall be permanently reduced in such country by [*].

(b)**Third Party Payments**. If Day One or any of its Affiliates or Sublicensees obtains a license or right to any Patent Rights from a Third Party in a country in the Day One Territory that is [*], then Day One shall have the right to credit or deduct [*] actually paid by Day One or any of its Affiliates or Sublicensees to such Third Party for such license or right to the extent reasonably allocable to such Licensed Product in such country ("**Third Party Payments**") against the royalties payable to MabCare pursuant to Section 6.4.1 with respect to such Licensed Product in such country. If Day One is not able to fully credit or deduct any such Third Party Payments in a given Calendar Quarter, then Day One shall be entitled to carry forward such right of credit or deduction to future Calendar Quarters with respect to such excess amount and continue applying such credit or deduction on a Calendar Quarterly basis thereafter until fully utilized or, if earlier, the expiration of the Royalty Term for such Licensed Product in such country.

(c)**Biosimilar Product**. On a Licensed Product-by-Licensed Product and country-by-country basis in the Day One Territory, if during a Calendar Quarter one or more Biosimilar Products are being sold in such country and Net Sales of the Licensed Product in such country during such Calendar Quarter are reduced [*], then the royalty rates set forth in Section 6.4.1 for such Licensed Product shall be reduced in such country [*].

(d) **Inflation Reduction Act Royalty Adjustments**. If, during the Royalty Term for a Licensed Product, such Licensed Product is designated as a "selected drug" by the Secretary of the U.S. Department of Health and Human Services, and Day One is required to negotiate a maximum fair price that shall apply to sales of such Licensed Product during the price applicability period as specified in the Inflation Reduction Act, then the applicable royalty rates set forth in Section 6.4.1 payable to MabCare for the Net Sales of such Licensed Product in the United States shall be reduced [*].

(e)**Deduction Floor**. Notwithstanding anything contained herein to the contrary, in no event will the aggregate royalty payment in respect of any Licensed Product in any Calendar Quarter in a country by Day One to MabCare hereunder be reduced to less than [*].

(f) **Compulsory Licenses for Licensed Product**. In the event that a Governmental Authority requires Day One or any of its Affiliates or Sublicensees to grant a compulsory license to a Third Party that permits such Third Party to make, sell, or otherwise commercially exploit a Licensed Product in a country in the Day One Territory, then the royalty rates in Section 6.4.1 for such Licensed Product in that country shall be reduced to [*].

(g)**Specific Patent Right Payments and Specified Patent Rights Costs.** [*]

6.5Sublicensing Income. If, [*], Day One or any Affiliate of Day One enters into any Sublicense with a Third Party, then Day One shall pay to MabCare [*].

6.6Payment Terms.

6.6.1**Development/Commercial Milestone Payments**. Day One shall provide MabCare with written notice of the achievement of each Development/Commercial Milestone Event [*]. Following receipt of such notification, MabCare shall invoice Day One for the amount of the applicable Development/Commercial Milestone Payment, and Day One shall make the corresponding Development/Commercial Milestone Payment [*].

6.6.2**Sales Milestone Payments and Royalty Payments**. During the Term, following the First Commercial Sale of a Licensed Product in the Day One Territory, Day One shall provide MabCare with a written report for each Calendar Quarter showing the Net Sales of each Licensed Product in the Day One Territory during the reporting Calendar Quarter and the royalties payable under this Agreement pursuant to Section 6.4. Each such report shall include, on a Licensed Product-by-Licensed Product basis: (a) the total gross amount invoiced for each Licensed Product sold; (b) the Net Sales of each Licensed Product; and (c) the royalties (in Dollars) payable and in total for all Licensed Products. Such reports shall also include notice of any Sales Milestone Event achieved during such Calendar Quarter (if any). Such reports shall be due [*]. The corresponding Sales Milestone Payment(s) and royalties shown to have accrued by a report provided under this Section 6.6.2 shall be due and payable on the date that such report is delivered.

6.7Payment Currency; Exchange Rate; Offset. All payments to be made under this Agreement shall be made in USD. Payments to a Party shall be made by electronic wire transfer of immediately available funds to the account of the other Party, as designated in writing to the paying Party. Payment to MabCare shall be made to the following account unless otherwise notified by MabCare in writing:

[*]

If any currency conversion is required in connection with the calculation of amounts payable hereunder, such conversion shall be made using a rate of exchange by using the arithmetic mean of the exchange rates for the purchase of Dollars as published in *The Wall Street Journal*, Eastern Edition, on the last Business Day of each month in the Calendar Quarter to which such payments relate.

6.8Late Payments. Any undisputed payments or portions thereof due hereunder that are not paid on the date such payments are due under this Agreement shall bear interest at a rate equal to the lesser of: (a) one (1) percentage point above the prime rate as published by The Wall Street Journal or any successor thereto on the first day of each Calendar Quarter in which such payments are overdue or (b) the maximum rate permitted by Applicable Law; in each case calculated on the number of days such payment is delinquent (provided that if the payment is disputed, such interest shall be calculated within thirty (30) days from the time that the dispute is resolved), compounded monthly. Notwithstanding the foregoing, [*]

6.9Payments to Third Parties.

6.9.1 MabCare shall be solely responsible for all payments (including all upfront payments, development, regulatory and sales milestones, royalty payments and any sharing of any sublicensing income) due under the Existing Agreements or to any Third Party that licensed or otherwise granted rights to MabCare or any of its Affiliates to any MabCare Patents or MabCare Know-How as of the Effective Date with respect to Day One's Development, Manufacture, or Commercialization of Licensed Compounds and Licensed Products in the Day One Territory in accordance with the terms of this Agreement.

6.9.2 Day One shall be solely responsible for all payments (including all upfront payments, development, regulatory and sales milestones, royalty payments and any sharing of any sublicensing income) due under any agreement between Day One and its Affiliates, on the one hand, and a Third Party, on the other hand, pursuant to which such Third Party licenses, grants, has licensed or otherwise has granted rights to Day One or any of its Affiliates to such Third Party's intellectual property with respect to Day One's Development, Manufacture, or Commercialization of Licensed Compounds and Licensed Products in the Day One Territory, [*].

6.9.3 Notwithstanding Section 6.9.1, if any Existing Agreement is terminated prior to its expiration due to MabCare's breach of such Existing Agreement or insolvency of MabCare (and not due to Day One's breach of the applicable provisions under such Existing Agreement or this Agreement), and it is necessary for Day One to obtain a sublicense of the rights under such terminated Existing Agreement, then[*]

6.10 Records and Audit Rights. Day One shall keep complete, true and accurate books and records for the purpose of determining the amounts payable under this Agreement. Such books and records shall be kept by Day One [*]. Day One shall make such accounting records available, on reasonable notice sent by MabCare, for inspection [*], by an independent certified public accounting firm nominated by MabCare and reasonably acceptable to Day One, for the purpose of verifying the accuracy of any statement or report given by Day One and to verify the accuracy of the payments due hereunder for any Calendar Year. Such auditor shall advise the Parties simultaneously promptly upon its completion of its audit whether or not the payments due hereunder have been accurately recorded, calculated, and reported, and, if not, the amount of such discrepancy. Except in the case of willful misconduct or fraud, [*]. The auditor shall be required to keep confidential all information learned during any such inspection, and to disclose to MabCare only such details as may be necessary to report the accuracy of Day One's statement or report. MabCare shall be responsible for the auditor's costs, unless the auditor certifies an underpayment by Day One that resulted from a discrepancy in a report that Day One provided to MabCare during the applicable audit period, which underpayment was more than [*] of the amount set forth in such report, in which case Day One shall bear the full cost of such audit. If such accounting firm identifies a discrepancy made during such period, any unpaid amounts or overpaid amounts that are discovered shall be paid/refunded promptly but in any event within [*] of the date of delivery of such accounting firm's written report so correctly concluding, or as otherwise agreed upon by the Parties. MabCare shall treat all financial information subject to review under this Section 6.10 in accordance with the confidentiality and non-use provisions of Article 7, and shall cause its accounting firm to enter into an acceptable confidentiality agreement with Day One obligating it to retain all such information in confidence pursuant to such confidentiality agreement. [*], royalty calculations with respect to such Calendar Year shall be binding and conclusive upon both Parties.

Unless an audit is ongoing with respect to such period, Day One shall be released from any liability or accountability with respect to said calculations for such Calendar Year.

6.11Taxes.

6.11.1**Withholding Taxes Generally**. Except as set forth in this Section 6.11, each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the activities of the Parties under this Agreement. To the extent Day One is required by Applicable Law to withhold any taxes, duties, levies, imposts, assessments, deductions, fees, and other similar charges by Applicable Law or any Governmental Authority ("**Withholding Taxes**") on any payment to MabCare, then Day One will pay such Withholding Taxes to the applicable Governmental Authority, will make the payment to MabCare of the net amount due after deduction or withholding of such taxes and will secure and, upon timely making such Withholding Taxes, promptly send to MabCare written evidence of such payment, as well as other information reasonably necessary for MabCare to substantiate the amount of taxes withheld. If Day One intends to withhold any taxes from any payment under this Agreement, Day One shall inform MabCare reasonably in advance of making such payment to permit MabCare an opportunity to provide any forms or information or obtain any taxing authority exemption or reduction as may be available to reduce or eliminate such withholding. In determining the amount to be withheld, Day One shall apply the reduced rate of withholding, or not withhold, as the case may be reflected in a properly executed IRS Form W-8BEN-E (or other appropriate form) received by Day One prior to the time that Day One makes any payment under this Agreement. In addition, Day One agrees to reasonably cooperate with MabCare in claiming refunds or exemptions from such deductions or withholdings under any relevant agreement or treaty which is in effect to ensure that any amounts required to be withheld pursuant to this Section 6.11.1 are reduced in amount to the fullest extent permitted by Applicable Law. MabCare shall not be responsible for any penalties or interests resulting from the failure by Day One to collect or remit any such Withholding Taxes. For clarity, any amounts withheld or deducted for taxes in accordance with this Section 6.11.1 shall be considered as having been paid to MabCare for purposes of this Agreement.

6.11.2**Withholding Action**. Notwithstanding the foregoing, if, as a result of a Withholding Action by Day One, withholding is required by Applicable Laws with respect to any payment made by Day One to MabCare pursuant to this Agreement and the amount of such withholding exceeds the amount of withholding that would have been required with respect to such payment under Section 6.11.1 if Day One had not committed the Withholding Action, then Day One shall pay an additional amount to MabCare such that, after withholding from such payment contemplated by this Agreement and such additional amount, MabCare receives the same amount with respect to such payment as it would have received from Day One absent such Withholding Action by Day One; provided, however, that if MabCare also has undertaken a Withholding Action that has caused the withholding required by Day One to increase, Day One shall only be required to pay to MabCare the increased amount to the extent attributable to its own Withholding Action (and not to MabCare's Withholding Action). For purposes of this Section 6.11.2, "**Withholding Action**" means, in the case of Day One or MabCare, as the case may be, (a) a permitted assignment or sublicense of this Agreement (in whole or in part) by Day One or MabCare, as the case may be, to an Affiliate or a Third Party outside of Day One's or MabCare's, as the case may be, then-current jurisdiction; or (b) a redomiciliation of Day One or MabCare, as the case may be to, or

payment made by or on behalf of Day One from or received by or on behalf of MabCare, in a jurisdiction outside Day One's or MabCare's, as the case may be, then-current jurisdiction of residence.

6.11.3**VAT**. All payments under this Agreement are exclusive of any value added, sales and use, excise, stamp, or similar country-specific, governmental or local taxes (collectively, "**VAT**"). If any VAT is required in respect of any payments under Applicable Law paid to the Party making the supply or providing the service, the Party making such payment shall pay VAT at the applicable rate in respect of any such payments upon the receipt of a valid VAT invoice in the appropriate form issued in respect of those payments, such VAT to be payable on the due date of the payments to which such VAT relates. For clarity, the paying Party shall not deduct any payment of VAT against the payments due to the other Party hereunder. The Parties will reasonably cooperate to issue valid VAT invoices for all amounts due under this Agreement consistent with VAT requirements. A Party shall not be responsible for any penalties and interest resulting from the failure by the other Party to collect (if not included on a valid VAT invoice) or remit any such VAT. The Parties shall reasonably cooperate to report and claim refunds or exemptions from any such VAT imposed on the transactions contemplated in this Agreement to the fullest extent permitted by Applicable Law and to timely file all required VAT tax returns.

6.12 Blocked Currency. If due to Applicable Law in a country or other jurisdiction in the Territory, it becomes impossible or illegal for Day One to transfer, or have transferred on its behalf, payments owed to MabCare under this Agreement with respect to such country, then Day One shall promptly notify MabCare and, thereafter, amounts accrued in such country under this Article 6 shall be paid to MabCare (or its designee) in such country in local currency by deposit in a local bank designated by MabCare and to the credit of MabCare, unless the Parties otherwise agree.

ARTICLE 7
CONFIDENTIALITY

7.1 Confidential Information. For purposes of this Agreement, "**Confidential Information**" of a Party means any and all confidential or proprietary information and data, including all Know-How and other scientific, pre-clinical, clinical, regulatory, manufacturing, marketing, financial and commercial information or data, whether or not patentable and in any form (written, oral, photographic, electronic, magnetic, or otherwise), including information of Third Parties, that a Party (or an Affiliate or representative of such Party) discloses or otherwise makes available to the other Party (or to an Affiliate or representative of such Party) in connection with this Agreement. The terms and conditions of this Agreement shall be the Confidential Information of both Parties. Notwithstanding the above, MabCare Know-How specific to the Licensed Compounds and Licensed Products shall be deemed to be the Confidential Information of both Parties, provided that, for clarity, [*].

7.2 Duty of Confidence; Exceptions. Each Party agrees that, during the Term and for a period of [*] thereafter, it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement (including for the exercise of the rights and licenses granted to such Party hereunder) any Confidential Information of the other Party, except to the extent expressly agreed in writing by the other Party. The

foregoing confidentiality and non-use obligations shall not apply with respect to any information that the receiving Party can demonstrate by competent written proof:

7.2.1 was in the lawful knowledge and possession of the receiving Party prior to the time it was disclosed by the disclosing Party to the receiving Party, or was otherwise developed independently by or for the receiving Party without use of or reference to the disclosing Party's Confidential Information, as evidenced by written records kept in the ordinary course of business, or other documentary proof of actual use by the receiving Party;

7.2.2 was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

7.2.3 became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement; or

7.2.4 was disclosed to the receiving Party, other than under an obligation of confidentiality, by a Third Party who has no confidentiality obligation with respect to the information so disclosed.

Any combination of features shall not be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the receiving Party.

7.3 Authorized Disclosures. Notwithstanding Section 7.2, the receiving Party may disclose the disclosing Party's Confidential Information if and to the extent such disclosure is reasonably necessary in the following instances:

7.3.1 to Governmental Authorities in connection with (a) filing, prosecuting, maintaining or listing Patent Rights in accordance with Article 8 or (b) obtaining and maintaining Regulatory Approval for the Licensed Compounds and Licensed Products as permitted by this Agreement;

7.3.2 prosecuting or defending litigation as contemplated herein;

7.3.3 subject to Section 7.5.2, to comply with Applicable Law;

7.3.4 to its actual or potential bona fide acquirors, investors, lenders or other similar sources of financing solely for the purpose of evaluating or carrying out an actual or potential investment, or acquisition;

7.3.5 to its external attorneys, independent accountants or financial advisors for solely for the purpose of enabling such attorneys, independent accountants or financial advisors to provide advice to it; and

7.3.6 to its Affiliates, employees, consultants and agents and actual or potential Sublicensees (in the case of Day One), or (sub)licensees (in the case of MabCare), collaborators

or contractors to exercise its rights or perform its obligations in accordance with the terms of this Agreement, or, in the case of MabCare, to Hyslink to the extent necessary to satisfy MabCare's obligations under the Hyslink License Agreement;

provided that in each of the cases of Sections 7.3.4-7.3.6 such Person is subject to a written agreement containing obligations of confidentiality and non-use at least as stringent as those herein (or without such agreement for recipients that are financial or legal advisors under a professional code of conduct giving rise to an expectation of confidentiality and non-use at least as restrictive as those set forth in this Agreement), and with respect to investors and lenders, with a customary period of confidentiality. Notwithstanding the foregoing, in the event that a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Sections 7.3.1-7.3.3, it will, except where impracticable or not legally permitted, promptly inform the other Party of the disclosure that is being sought in order to provide the other Party an opportunity to challenge or limit the disclosure obligations, and, if requested by the other Party, cooperate in all reasonable respects with the other Party's efforts to obtain confidential treatment or a protective order with respect to any such disclosure, at the other Party's expense. In any such event, each Party agrees to take all reasonable action to minimize disclosure of the other Party's Confidential Information. Any information disclosed pursuant to this Section 7.3 shall remain, subject to Section 7.2, the Confidential Information of the disclosing Party and subject to the restrictions set forth in this Agreement, including the foregoing provisions of this Article 7.

7.4 Prior Confidentiality Agreement. This Agreement supersedes that certain [*] (the "**CDA**"). All information exchanged between the Parties under the CDA shall be deemed to have been disclosed under this Agreement and shall be subject to the terms of this Article 7.

7.5Public Disclosures; Securities Filings.

7.5.1**Press Release**. The Parties agree that Day One may issue a press release substantially in the form of Schedule 7.5.1 with respect to this Agreement and following Day One's issuance thereof either Party may make subsequent public disclosure of the contents of such press release so long as the information disclosed remains true and accurate. Each Party agrees not to issue any press release or other public statement, whether oral or written, disclosing the terms hereof or any of the activities conducted hereunder without the prior written consent of the other Party (such consent not to be unreasonably withheld, conditioned or delayed), except as provided herein; provided, however, that (a) neither Party shall be prevented from complying with any duty of disclosure it may have pursuant to Securities Regulations, and (b) Day One shall have the right to make public announcements regarding the achievement of any material events regarding the progress of the Development and Commercialization of the Licensed Compounds and Licensed Products under this Agreement, as well as the achievement of Development/Commercial Milestone Events.

7.5.2**Securities Filings**. Notwithstanding anything herein to the contrary, either Party or its Affiliates may disclose the relevant terms of this Agreement to the extent required or advisable to comply with the rules and regulations promulgated by the U.S. Securities and Exchange Commission or any equivalent governmental agency in any country in the Territory, or with the rules of any stock exchange on which such Party's (or such Party's Affiliates') securities are listed (such rules and regulations "**Securities Regulations**" and each such entity a "**Securities**

Regulator"). If a Party is required by Applicable Law to submit a description of the terms of this Agreement to or file a copy of this Agreement with any Securities Regulator, such Party agrees to reasonably consult and coordinate with the other Party with respect to such disclosure and, if applicable, the preparation and submission of a confidential treatment request for this Agreement. Notwithstanding the foregoing, if a Party is required by Applicable Law to submit a description of the terms of this Agreement to or file a copy of this Agreement with any Securities Regulator and such Party has (i) promptly notified the other Party in writing of such requirement and any respective timing constraints, (ii) provided copies of the proposed disclosure or filing to the other Party reasonably in advance of such filing or other disclosure and (iii) given the other Party a reasonable time under the circumstances to comment upon and request confidential treatment for such disclosure, then such Party will have the right to make such disclosure or filing at the time and in the manner reasonably determined by its counsel to be required by Applicable Law or the applicable Securities Regulator. If a Party seeks to make a disclosure or filing as set forth in this Section 7.5.2 and the other Party provides comments within the respective time periods or constraints specified herein, the Party seeking to make such disclosure or filing will reasonably consider such comments and use good faith efforts to incorporate such comments in the disclosure or filing; provided that prior to making any such filing of this Agreement, the Parties shall reasonably cooperate and use good faith efforts to agree on a redacted form of this Agreement to be so filed.

7.5.3 **Use of Names**. Except as may be otherwise provided herein, neither Party nor its Affiliates shall use the corporate marks or any other name or trademark of the other Party, its Affiliates or their respective employees in any publicity, promotion, news release or disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other Party, except as may be required by Applicable Law.

7.6 Publications. In the event a Party desires to publicly present or publish an article or other publication regarding the Licensed Compounds or Licensed Products (each such proposed presentation or publication, a "**Proposed Publication**"), such Party shall provide the other Party (via the JSC) with a copy of such Proposed Publication [*] (as to either, the "**Review Period**") prior to the intended submission or presentation date. A Party agrees that it will not submit or present any Proposed Publication (a) until the other Party has provided written comments during such Review Period on the material in such Proposed Publication or (b) until the applicable Review Period has elapsed without written comments from the other Party, in which case such Party may proceed and the Proposed Publication will be considered approved in its entirety. If the proposing Party receives written comments from the other Party during the applicable Review Period, it shall consider the comments of the other Party in good faith, but will retain the sole authority to submit the manuscript for such Proposed Publication; provided that the proposing Party agrees to (i) delete any Confidential Information of the other Party that the other Party identifies for deletion in its written comments, and (ii) delay such Proposed Publication for [*] to enable the other Party to draft and file Patent Rights with respect to any subject matter to be made public in such Proposed Publication and to which the other Party has the applicable intellectual property rights to file such Patent Rights. The Proposing Party shall provide the other Party a copy of the Proposed Publication at the time of the submission or presentation. Notwithstanding the foregoing, Day One shall have the right to make scientific publication about Clinical Trials for the Licensed Products in the Day One Territory, including the results of such Clinical Trials, provided that, [*]. A Party shall require

its Affiliates, Sublicensees and subcontractors to comply with the obligations of this Section 7.6 as if they were such Party, and shall be liable for their non-compliance.

7.7 Re-Publication. Notwithstanding anything to the contrary in this Article 7, the contents of any press release or other publication that has been reviewed and approved by a reviewing Party in accordance with this Article 7 may be re-released by such reviewing Party or publishing Party without a requirement for re-approval.

ARTICLE 8
INTELLECTUAL PROPERTY

8.1 Ownership.

8.1.1 **Foreground Know-How**. Inventorship of Foreground Know-How and all intellectual property rights therein shall be determined in accordance with principles of inventorship for Patent Rights and other intellectual property under U.S. law, and ownership shall follow inventorship. As between the Parties, (a) MabCare shall solely own all MabCare Foreground Know-How and MabCare Foreground Patents, (b) Day One shall solely own all Day One Foreground Know-How and Day One Foreground Patents, and improvements solely with respect to Day One Background Know-How (which MabCare hereby assigns to Day One) and (c) the Parties will each own an equal, undivided interest in any and all Joint Foreground Know-How and Joint Foreground Patents. Subject to terms and conditions of this Agreement, including the licenses granted in Section 2.1 and Section 2.2, each Party shall have the right to use and exercise its ownership rights in and to any and all Joint Foreground Know-How and Joint Foreground Patents without an accounting or obligation to, or consent required from, the other Party, [*].

8.1.2 **Assignment; Cooperation**. Each Party shall (and shall cause its Affiliates to) cause all of its directors, officers, employees, contractors, agents and any others who perform activities for it (or its Affiliates) under this Agreement to be under an obligation to assign to such Party (or its Affiliate) their rights in and to any Foreground Know-How and all intellectual property rights therein, except where Applicable Law requires otherwise. Each Party shall provide the other Party all reasonable assistance and cooperation in the Prosecution and Maintenance of Patent Rights pursuant to this Article 8, including providing any necessary powers of attorney, oaths, declarations, assignments, and executing any other required documents or instruments. With respect to Joint Foreground Patents, MabCare Foreground Patents and Day One Foreground Patents, the Parties intend to Prosecute and Maintain such Patent Rights such that [*].

8.2 Patent Prosecution and Maintenance.

8.2.1 **MabCare Patents in the Day One Territory**.

(a) Day One shall have the first right to control the Prosecution and Maintenance of (a) [*] (the "**MabCare PCT**"), and (b) any other MabCare Patents (for clarity, including MabCare Foreground Patents) in the Day One Territory, at Day One's cost. Day One shall keep MabCare reasonably informed of the status of the Prosecution and Maintenance of the MabCare PCT and other MabCare Patents in the Day One Territory, including that Day One will [*]. If Day One determines to abandon or otherwise not Prosecute and Maintain any pending or

issued MabCare Patent in the Day One Territory, [*].

(b)With respect to [*].

8.2.2 **MabCare Patents**. Subject to Section 8.2.1, MabCare shall have the sole right to control the Prosecution and Maintenance of the MabCare Patents (including MabCare Foreground Patents) in the MabCare Territory, at MabCare's cost. MabCare shall keep Day One reasonably informed of the status of the Prosecution and Maintenance of the MabCare Patents in the MabCare Territory, including that MabCare will [*].

8.2.3**Day One Patents**. Subject to the remainder of this Section 8.2.3, Day One shall have the right, but not the obligation, to Prosecute and Maintain the Day One Patents (including any Day One Foreground Patents) worldwide, [*]

8.2.4**Joint Foreground Patents**. Day One shall have the first right, but not the obligation, to Prosecute and Maintain the Joint Foreground Patents in the MabCare Territory and Day One Territory in both Parties' names, and the Parties shall [*].

8.3Cooperation for Patent Extensions. Day One shall have the sole right to determine whether or not to seek or obtain any patent term extensions, adjustments or restorations under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984, any Supplementary Certificate of Protection of the member states of the European Union or similar right in any country or jurisdiction outside of the United States or European Union (any such right, a "**Patent Term Extension**") for the (a) MabCare Patents and Joint Foreground Patents in the Day One Territory with respect to the Licensed Compounds and Licensed Products, and (b) Day One Patents worldwide. Except as otherwise provided herein, MabCare shall have the sole right to determine whether or not to seek or obtain any Patent Term Extension for the MabCare Patents and Joint Foreground Patents (for clarity, with respect to the Joint Foreground Patents, in the MabCare Territory with respect to the Licensed Compounds and Licensed Products). Each Party shall promptly cooperate with the other Party in obtaining any such Patent Term Extension for a Patent Right as set forth above, at the requesting Party's cost, including executing any authorization or instruments, make any filings, or take such further actions as may be requested to implement and obtain any such Patent Term Extension.

8.4Purple Book Listings. Day One shall have the sole right and authority to list or de-list any MabCare Patents, Day One Patents and Joint Foreground Patents in the Day One Territory, in the FDA's "Purple Book" or any ex-U.S. equivalent thereto with respect to the Licensed Products. MabCare shall have the sole right and authority to list or de-list any MabCare Patents, Day One Foreground Patents and Joint Foreground Patents in the MabCare Territory in any equivalent to the FDA's "Purple Book" with respect to the Licensed Products. Each Party shall reasonably cooperate with the other Party in making or withdrawing any such listing for a Patent Rights as set forth above, at the requesting Party's cost, including applying for such patent listing and signing all necessary documents.

8.5 Common Interest Disclosures. With regard to any information or opinions exchanged pursuant to this Agreement by the Parties (or their Affiliates) regarding intellectual property owned by Third Parties, the Parties agree that they have a common legal interest in

coordinating Prosecution and Maintenance of their respective Patent Rights, as set forth in this Article 8, and in determining whether, and to what extent, Third Party intellectual property rights may affect the conduct of the Development, Manufacturing or Commercialization of Licensed Compounds and Licensed Products, and have a further common legal interest in defending against any actual or prospective Third Party claims based on allegations of misuse or infringement of intellectual property rights relating to the Development, Manufacturing or Commercialization of Licensed Compounds and Licensed Products. Accordingly, Day One and MabCare agree that all such information and materials obtained by Day One or MabCare from each other will be used solely for purposes of the Parties' common legal interests with respect to the conduct of the Agreement. All information and materials will be treated as protected by the attorney-client privilege, the work product privilege, and any other privilege or immunity that may otherwise be applicable. By sharing any such information and materials, neither Party intends to waive or limit any privilege or immunity that may apply to the shared information and materials. Neither Party shall have the authority to waive any privilege or immunity on behalf of the other Party without such other Party's prior written consent, nor shall the waiver of privilege or immunity resulting from the conduct of one Party be deemed to apply against any other Party.

8.6Patent Enforcement.

8.6.1 **Notice**. Each Party shall notify the other [*] of becoming aware of any alleged or threatened infringement by a Third Party of any MabCare Patent, Day One Foreground Patent or Joint Foreground Patent which infringement adversely affects or could reasonably be expected to adversely affect the Development, Manufacture, or Commercialization of any Licensed Compound or Licensed Product in the Field in the Territory, or any related declaratory judgment or equivalent action alleging the invalidity, unenforceability or non-infringement of any such Patent Right ("**Competitive Infringement**").

8.6.2**Enforcement**.

(a)Day One or its designee shall have the first right, but not the obligation, to bring and control any legal action to enforce the MabCare Patents and Joint Foreground Patents with respect to a Competitive Infringement in the Day One Territory (such action an "**Enforcement Action**"), [*]. Day One shall keep MabCare reasonably informed as to the status of any such Enforcement Action. If Day One or its designee fails to file an Enforcement Action with respect to, or fails to take steps to abate, a Competitive Infringement in the [*] then MabCare shall have the right, but not the obligation, to bring and control an Enforcement Action for the MabCare Patents and Joint Foreground Patents with respect to such Competitive Infringement, [*].

(b)MabCare or its designee shall have the first right, but not the obligation, to bring and control any Enforcement Action for the Day One Foreground Patents and Joint Foreground Patents with respect to a Competitive Infringement in the MabCare Territory, [*]. MabCare shall keep Day One reasonably informed as to the status of any such Enforcement Action. If MabCare or its designee fails to file an Enforcement Action with respect to, or fails to take steps to abate, a Competitive Infringement in the Territory [*] then Day One shall have the right, but not the obligation, to bring and control an Enforcement Action for the Day One Foreground Patents and Joint Foreground Patents with respect to such Competitive Infringement

[*].

(c) **Cooperation**. In a connection with any Enforcement Action, each Party shall provide the enforcing Party with all reasonable assistance in such action, at the enforcing Party's request and expense, including joining such Enforcement Action if required by law or at the reasonable request of the enforcing Party and providing access to relevant documents and other evidence, and making its employees reasonably available during business hours. The non-enforcing Party shall be entitled to separate representation in an Enforcement Action by counsel of its own choice and at its own cost and expense, but such Party shall at all times cooperate fully with the enforcing Party.

(d) **Settlement**. A settlement, consent judgment or other voluntary final disposition of a Competitive Infringement may be entered into by the enforcing Party without the consent of the non-enforcing Party; provided, however, that any such settlement, consent judgment or other disposition shall not, without the prior written consent of the non-enforcing Party, [*].

(e) **Recoveries**. Any recoveries resulting from an Enforcement Action brought pursuant to Section 8.6.2(a) or Section 8.6.2(b) shall [*].

8.6.3 **Joint Foreground Patents (Other Infringement)**. Each Party shall notify the other [*] of becoming aware of any alleged or threatened infringement by a Third Party of any Joint Foreground Patent[*].

8.6.4 **Day One Patents**. Subject to Section 8.6.2(b), as between the Parties, Day One shall have the sole right, but not the obligation, to enforce the Day One Patents or take any steps to abate an alleged or actual Third Party infringement of any Day One Patent worldwide, [*].

8.6.5 **MabCare Patents**. As between the Parties, MabCare shall have the sole right, but not the obligation, to enforce the MabCare Patents or take any steps to abate an alleged or actual Third Party infringement of any MabCare Patent in the MabCare Territory[*].

8.7 Infringement of Third Party Rights.

8.7.1 **Notice**. Each Party shall promptly notify the other Party in writing [*] after receiving a notice of a claim or assertion that any Licensed Compound or Licensed Product, or any MabCare Technology, Day One Technology or Joint Foreground IP infringes or misappropriates any Third Party's Patent Rights or other intellectual property rights in any country ("**Third Party Infringement Claim**"), [*].

8.7.2 **Defense**[*] as between the Parties, the alleged infringing Party shall have the right, but not the obligation, [*] to control the defense and settlement of such Third Party Infringement Claim, [*]

8.8 Patents Licensed From Third Parties. Notwithstanding anything to the contrary herein, the Parties agree and acknowledge that, Day One's rights under Section 8.2, Section 8.3, Section 8.4, Section 8.6 and Section 8.7 with respect to any MabCare Patent that is licensed by MabCare pursuant to the Hyslink License Agreement (each, a "**Hyslink Licensed Patent**") shall

be subject to the rights retained by Hyslink pursuant the Hyslink License Agreement. Without limiting the foregoing, [*].

8.9 Patent Marking. Day One shall mark all Licensed Products in accordance with the applicable patent marking laws and shall require all of its Affiliates and Sublicensees to do the same.

8.10 Trademarks. Day One will solely own all right, title and interest in and to any trademarks adopted for use with the Licensed Products in the Field ("**Product Trademarks**") in the Day One Territory, and will be responsible for the selection, registration, filing, maintenance and enforcement thereof. MabCare will solely own all right, title and interest in and to any Product Trademarks in the MabCare Territory, and will be responsible for the selection, registration, filing, maintenance and enforcement thereof. Each Party will consider in good faith comments of the other Party regarding the Product Trademarks. Neither Party nor any of its Affiliates will at any time do or authorize to be done any act or thing which is likely to materially impair the rights of the other Party's trademarks or interests therein, and will not at any time claim any right of interest in or to such marks or the registrations or applications therefor. Neither MabCare nor any of its Affiliates will use Day One's or any of its Affiliates' trademarks or any trademark that is confusingly similar thereto.

ARTICLE 9
REPRESENTATIONS, WARRANTIES, AND COVENANTS

9.1 Representations, Warranties of Each Party. Each Party represents and warrants to the other Party, as of the Effective Date, that:

9.1.1 it is duly organized, validly existing and in good standing in its jurisdiction of organization;

9.1.2 it has full corporate power and authority to execute, deliver and perform this Agreement, and has taken all corporate action required by Applicable Laws and its organizational documents to authorize the execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement;

9.1.3 this Agreement has been duly executed by it and is legally binding upon it and enforceable in accordance with its terms, subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance and general principles of equity (whether enforceability is considered a proceeding at law or equity); and

9.1.4 the execution and delivery of this Agreement and all other instruments and documents required to be executed pursuant to this Agreement, the contemplated performance of its covenants and responsibilities hereunder, and the consummation of the transactions contemplated hereby do not and shall not (a) conflict with or result in a breach of any provision of its organizational documents, (b) result in a breach of any agreement to which it or its Affiliate is a party, or (c) violate any Applicable Laws.

9.2 Representations and Warranties of MabCare. MabCare represents and warrants to Day One, as of the Effective Date, that:

9.2.1 MabCare has the right, power and authority to grant the rights and licenses granted to Day One hereunder, and MabCare is the sole and exclusive owner of, or otherwise Controls, the MabCare Technology licensed to Day One hereunder;

9.2.2 the MabCare Technology comprises all Patents and Know-How Controlled by MabCare which are necessary or reasonably useful for the Development, Manufacture, Commercialization or exploitation of the Licensed Compounds and Licensed Products in the Day One Territory as contemplated herein;

9.2.3 except as set forth in Schedule 9.2.3, none of the licenses or rights granted by MabCare to Day One under this Agreement as of the Effective Date are subject to any in-license or other similar agreement with another Person regarding any intellectual property rights licensed hereunder;

9.2.4 neither MabCare nor any of its Affiliates have (a) granted any license, covenant not to sue, waiver, or other right under the MabCare Technology, or with respect to the Licensed Compounds or Licensed Products, that is inconsistent with the license and rights granted to Day One hereunder, and the MabCare Technology, Licensed Compounds and Licensed Products are free and clear of liens, charges and encumbrances, or (b) entered into any settlement, non-competition agreement, restrictive covenant, or any other agreement restricting the ownership, use or exploitation of the MabCare Technology licensed to Day One hereunder or the Licensed Compounds or Licensed Products;

9.2.5 there are no restrictions or requirements of any Governmental Authority or any Person that provided funding to MabCare or its Affiliates, that (a) prevent, preclude or restrict MabCare from granting the license under the MabCare Technology granted to Day One hereunder, or transferring to Day One any of the MabCare Technology, the MabCare Materials, Existing Inventory or the Licensed Compounds as set forth in this Agreement or (b) otherwise encumber Day One's practice of the license and rights granted to Day One under this Agreement;

9.2.6 (a) no Governmental Authority has any rights to the MabCare Technology licensed to Day One hereunder, and neither MabCare nor any of its Affiliates has any obligations to such entities with respect thereto, and (b) without limiting the foregoing (a), the MabCare Technology is not the subject of any licenses, options, or other rights of any Governmental Authority, within or outside the United States, due to such Governmental Authority's funding of research and development or otherwise;

9.2.7 Schedule 1.104 lists all MabCare Patents existing as of the Effective Date and all such Patent Rights listed on Schedule 1.104 (a) are either solely and exclusively owned by MabCare, or exclusively licensed to MabCare, in each case as indicated on Schedule 1.104, and (b) have been filed, prosecuted and maintained properly and correctly and in compliance with all Applicable Laws, including any duties of candor to applicable patent offices, and all applicable fees have been paid on or before any final due date for payment;

9.2.8 no claim or action has been brought or threatened in writing by any Third Party alleging that any of the MabCare Patents are invalid or unenforceable, and there are no pending, alleged or threatened, (a) *inter partes* reviews, post-grant reviews, interferences, re-examinations, or oppositions involving the MabCare Patents that are in or before any patent office (or other Governmental Authority performing similar functions) or (b) inventorship or ownership challenges involving the MabCare Patents that are in or before any patent office or other Governmental Authority;

9.2.9 to the Knowledge of MabCare, each MabCare Patent properly identifies the inventor(s) of the inventions claimed in such MabCare Patents, and each such inventor has assigned his or her entire right, title and interest in and to the applicable MabCare Patent to MabCare (or in the case of MabCare Patents exclusively licensed to MabCare as set forth on Schedule 1.104, the licensor of such Patent Right) and any instrument assigning such inventors' right, title and interest in such MabCare Patent is valid and enforceable;

9.2.10 (a) the Existing Agreements are in full force and effect, (b) MabCare and its Affiliates are in compliance in all material respects with the terms and conditions of each Existing Agreement, including any payment obligations thereunder, and (c) MabCare or its Affiliates have not received from or provided to any counterparty to an Existing Agreement any notice of breach or default, or asserting or requesting termination, of such Existing Agreement;

9.2.11 (a) the MabCare Manufacturing Agreements are in full force and effect, (b) MabCare and its Affiliates are in compliance in all material respects with the terms and conditions of each MabCare Manufacturing Agreement, including any payment obligations thereunder, and (c) MabCare or its Affiliates have not received from or provided to any counterparty to a MabCare Manufacturing Agreement any notice of breach or default, or asserting or requesting termination, of such MabCare Manufacturing Agreement;

9.2.12 other than [*], there are no agreements between MabCare and a Third Party pursuant to which MabCare engaged such Third Party to conduct any material Manufacturing-related activities for the Existing Inventory, Licensed Compounds or Licensed Products;

9.2.13 (a) to MabCare's Knowledge, the Existing Inventory includes all inventory of Licensed Product in the possession or control of MabCare or its Affiliates, and (b) neither MabCare nor its Affiliates are currently Manufacturing (i.e., with outstanding work orders) any Licensed Compound or Licensed Product either itself or themselves or through any Third Party;

9.2.14 MabCare has fulfilled all of its payment obligations under the Abmart Agreement, and (a) MabCare solely owns all right, title and interest in and to Ab13, and (b) MabCare has acquired the right to use the MabCare Materials as such MabCare Materials have been used as of the Effective Date, subject to the QuaCell Agreement and the Genomeditech Agreement, and;

9.2.15 there are no pending or threatened (in writing) claims, actions, suits or proceedings alleging that the MabCare Technology or the Licensed Compounds or Licensed Products, or any Development or Manufacture thereof conducted prior to the Effective Date, infringes or misappropriates the intellectual property rights of any Third Party, and to the

Knowledge of MabCare, no facts or circumstances exist that would reasonably be expected to give rise to any such claims, actions, suits or proceedings with respect to any issued Patent Rights, Know-How or other intellectual property of any Third Party existing as of the Effective Date;

9.2.16 to the Knowledge of MabCare, the use of the MabCare Technology (including the MabCare Materials, subject to the QuaCell Agreement and the Genomeditech Agreement), Existing Inventory, or Development, Manufacture or Commercialization of the Licensed Compounds and Licensed Products, in each case as contemplated under this Agreement (a) does not infringe any claim of an issued Third Party Patent Right, or (b) does not misappropriate any Know-How or other intellectual property of any Third Party;

9.2.17 to the Knowledge of MabCare, no Third Party is infringing or misappropriating, has infringed or misappropriated or is threatening to infringe or misappropriate the MabCare Patents or the MabCare Know-How, and neither MabCare nor any of its Affiliates has made a claim against a Third Party alleging that such Third Party is infringing or misappropriating or has infringed or has misappropriated any MabCare Patents or MabCare Know-How;

9.2.18 MabCare and its Affiliates have conducted the research and development program for CB-002, and all Development and Manufacturing of the Licensed Compounds and Licensed Products, in material compliance with Applicable Laws with respect to IND applications in the U.S. and Mainland China;

9.2.19 neither MabCare nor any of its Affiliates (a) are or have been at any time been debarred under 21 U.S.C. § 335a (or any foreign equivalent), or (b) are employing or using, or have employed or otherwise used, in any capacity the services of any person or entity debarred under 21 U.S.C. § 335a (or any foreign equivalent) in performing any research and development activities relating to the Licensed Compounds or Licensed Products;

9.2.20 neither MabCare nor any of its Affiliates, to the Knowledge of MabCare, nor any of its or their respective directors, officers or employees, have made a knowingly false or fraudulent statement to any Regulatory Authority with respect to the Development of the Licensed Compounds or Licensed Products, or knowingly failed to disclose a material fact required under Applicable Law to be disclosed to any Regulatory Authority with respect to the development of the Licensed Compounds or Licensed Products;

9.2.21 MabCare has disclosed or otherwise made available to Day One for review all material information and documents in MabCare's possession and control as of the Effective Date that pertain to any Licensed Compound or Licensed Product, or the exploitation thereof, and all such information and documents are accurate in all material respects;

9.2.22 (a) Schedule 9.2.22 sets forth all of the INDs, MAAs and Regulatory Approvals for the Licensed Compounds and Licensed Products, in the name of, or otherwise held by or on behalf of, MabCare or any of its Affiliates, (b) each of the INDs, MAAs and Regulatory Approvals set forth on Schedule 9.2.22 have been approved by the FDA or other applicable Regulatory Authority and are in full force and good standing, and (c) neither MabCare nor any of its Affiliates has received any notice in writing, or otherwise has knowledge of any facts, which

have, or would reasonably be expected to have, led MabCare (or its Affiliate) to believe that any of the INDs, MAAs or Regulatory Approvals relating to the Licensed Products are not currently in, or may not with the passage of time remain in, good standing with the FDA or other applicable Regulatory Authority;

9.2.23 MabCare has disclosed to Day One all material correspondence between MabCare (or any of its Affiliates) and the FDA, National Medical Products Administration (NMPA) or other Regulatory Authority regarding the Licensed Compounds and Licensed Products;

9.2.24 MabCare has disclosed to Day One complete and accurate copies of ([*];

9.2.25 the information and data for the Licensed Product submitted to the [*];

9.2.26 other than agreements with Third Party subcontractors (including a contract research organization and CMO), neither MabCare nor any of its Affiliates has granted a license or other right (including an option) to a Third Party, or is actively engaged in discussions with a Third Party for the grant of a license or other right (including an option) to such Third Party, under the MabCare Technology to Develop, Manufacture or Commercialize Licensed Compounds and Licensed Products in the Field in the MabCare Territory; and

9.2.27 there are no legal claims, judgments or settlements against or owed by MabCare or its Affiliates, or pending or threatened in writing, in each case relating to antitrust, anti-competition, anti-bribery or corruption violations.

9.3 Mutual Covenants. Each Party covenants to the other Party that in the course of performing its obligations or exercising its rights under this Agreement, such Party shall, and shall procure that such Party's Affiliates and (sub)licensees and subcontractors, comply with all Applicable Law, including, as applicable, GMP, GLP and GCP. Without limiting the foregoing, the Parties additionally agree as follows:

9.3.1 **Data Privacy**. Each Party shall: (a) comply with all Applicable Laws in relation to data protection, privacy, or restrictions on, or requirements in respect of, the processing of Personal Data of any kind, including the Health Insurance Portability and Accountability Act, General Data Protection Regulation (Regulation (EU) 2016/679) (GDPR), and any equivalent Applicable Law in any other jurisdiction (as any of the foregoing may be amended from time to time, collectively, "**Data Protection Laws**") with respect to the collection, use, transfer, storage, destruction, aggregation or other use of subject health information or other Personal Data (as defined in the applicable Data Protection Laws, collectively, "**Personal Data**") in connection with its activities under or in connection with this Agreement, including the Development and Commercialization of any Licensed Product hereunder; (b) implement appropriate and reasonable security processes and controls in connection with its activities under or in connection with this Agreement so as to protect the security and privacy of Personal Data in accordance with Data Protection Laws; and (c) take such steps as necessary to comply with Data Protection Laws to permit such Party to disclose Personal Data to the other Party and to permit the other Party to use and disclose such Personal Data for its own purposes in accordance with this Agreement. Without limiting the foregoing, if required by Applicable Law, the Parties will negotiate and enter into a

written agreement with respect to the collection, storage, transfer, processing and use of Personal Data by the Parties and their Affiliates as contemplated by this Agreement (the "**DPA**").

9.3.2 **No Debarment or Regulatory Sanction**. Neither Party shall employ (or, to its Knowledge, use any contractor, subcontractor, distributor or other Persons that provide services to such Party in connection with this Agreement that employs) any Person that is debarred, disqualified, blacklisted, banned or subject to any similar sanction by any applicable Regulatory Authority (including, as applicable, the FDA pursuant to its authority under Sections 306(a) and (b) of the FFDCA) or that is the subject of any investigation or proceeding which may result in debarment, disqualification, blacklisting, banning or any similar sanction by any applicable Regulatory Authority, in each case, in connection with the performance of its activities under this Agreement. Each Party shall notify the other Party in writing promptly if it or any such Person who is performing services hereunder is debarred, disqualified, blacklisted, banned or subject to any similar sanction by any applicable Regulatory Authority or becomes the subject of any such investigation or proceeding.

9.4 MabCare Covenants. MabCare hereby covenants to Day One during the Term that:

9.4.1 it shall remain in compliance in all material respects with each Existing Agreement, and it shall promptly provide to Day One a copy of any notice received from or provided to any counterparty to an Existing Agreement, including any notice of breach or default;

9.4.2 it shall not, and shall cause its Affiliates to not, without Day One's prior written consent, (i) terminate any Existing In License Agreement, or (ii) modify or amend, or waive any of its rights under, any Existing In License Agreement, in each case ((i) and (ii)) in a manner that could reasonably be expected to adversely affect any of Day One's rights or obligations under this Agreement;

9.4.3 it shall not, without Day One's prior written consent, assign or otherwise transfer or novate any Existing In License Agreement (or agree to do any of the foregoing) except in connection with a permitted assignment pursuant to Section 12.1;

9.4.4 during the time it has an obligation to supply and utilizes a MabCare Manufacturing Agreement to supply, the Licensed Product to Day One as provided herein or under the Clinical Supply Agreement, it shall remain in compliance in all material respects with such MabCare Manufacturing Agreement(s), and it shall promptly provide to Day One a copy of any notice received from or provided to any counterparty to a MabCare Manufacturing Agreement that would reasonably be expected to adversely affect MabCare's obligation to supply the Licensed Product to Day One, including any notice of breach or default;

9.4.5 during the time it has an obligation to supply and utilizes a MabCare Manufacturing Agreement to supply, the Licensed Product to Day One as provided herein or under the Clinical Supply Agreement, it shall not, and shall cause its Affiliates to not, without Day One's prior written consent, (i) terminate such MabCare Manufacturing Agreement(s), or (ii) modify or amend, or waive any of its rights under, such MabCare Manufacturing Agreement(s), in each case ((i) and (ii)) in a manner that could reasonably be expected to adversely affect any of Day One's

rights or obligations under this Agreement;

9.4.6 during the time it has an obligation to supply and utilizes a MabCare Manufacturing Agreement to supply, the Licensed Product to Day One as provided herein or under the Clinical Supply Agreement,, it shall not, without Day One's prior written consent (not to be unreasonably withheld, conditioned or delayed), assign or otherwise transfer or novate such MabCare Manufacturing Agreement(s) (or agree to do any of the foregoing), except in connection with a permitted assignment pursuant to Section 12.1;

9.4.7 it shall (and shall cause its Affiliate to) maintain in force all necessary consents, licenses, permits, approvals and other permissions to enable it to perform its obligations under this Agreement;

9.4.8 it will not (and will cause its Affiliates not to), without Day One's prior written consent, grant any liens or security interests with respect to any of the MabCare Technology in a manner that would conflict with or impair any of the rights or licenses granted to Day One hereunder;

9.4.9 it will not (and will cause its Affiliates not to), without Day One's prior written consent, grant to any Third Party any license or other right under the MabCare Technology that would conflict with or impair the rights or licenses granted to Day One hereunder; and

9.4.10 it will not (and will cause its Affiliates not to), without Day One's prior written consent, transfer or assign ownership of any MabCare Technology except in connection with a permitted assignment of this Agreement in accordance with Section 12.1.1.

9.5Day One Covenants. Day One hereby covenants to Mab Care during the Term that:

9.5.1 it shall, and shall cause its Affiliates and Sublicensees to, conduct any Development, Manufacturing, Commercialization and other exploitation of any Licensed Compounds and Licensed Product in accordance with all Applicable Laws;

9.5.2 it shall (and shall cause its Affiliate to) maintain in force all necessary consents, licenses, permits, approvals and other permissions to enable it to perform its obligations under this Agreement;

9.5.3 it will not (and will cause its Affiliates not to), without MabCare's prior written consent, grant to any Third Party any license or other right under the Day One Technology, that would conflict with or impair the rights or licenses granted to MabCare hereunder.

9.6No Other Warranties. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, (A) NO REPRESENTATION OR WARRANTY WHATSOEVER IS MADE OR GIVEN BY OR ON BEHALF OF DAY ONE, MABCARE OR THEIR RESPECTIVE AFFILIATES; AND (B) ALL OTHER WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE EXPRESSLY DISCLAIMED BY THE PARTIES, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY,

FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT. DAY ONE MAKES NO WARRANTY, EITHER EXPRESS OR IMPLIED, THAT ITS DEVELOPMENT, MANUFACTURING OR COMMERCIALIZATION EFFORTS FOR THE LICENSED COMPOUNDS OR LICENSED PRODUCTS WILL BE SUCCESSFUL OR ACHIEVE ANY PARTICULAR RESULT.

ARTICLE 10
INDEMNIFICATION

10.1 Indemnification by Day One. Day One shall defend, indemnify, and hold harmless MabCare, its Affiliates and its and their respective directors, officers, employees and agents (each, a "**MabCare Indemnitee**") from and against any and all liabilities, costs, expenses, and losses (including reasonable legal expenses and attorneys' fees) (collectively, "**Losses**"), to which any MabCare Indemnitee may become subject as a result of any claim, demand, action, or other proceeding by a Third Party (each, a "**Third Party Claim**") to the extent such Losses arise out of [*].

10.2 Indemnification by MabCare. MabCare shall defend, indemnify, and hold harmless Day One, its Affiliates, Sublicensees and its and their respective directors, officers, employees and agents (each, a "**Day One Indemnitee**") from and against any and all Losses to which any Day One Indemnitee may become subject as a result of any Third Party Claim to the extent such Losses arise out of [*].

10.3 Procedure.

10.3.1 **Notice**. The Party seeking indemnification under Section 10.1 or Section 10.2 (the "**Indemnified Party**") shall inform the other Party (the "**Indemnifying Party**") of the Third Party Claim giving rise to the obligation to indemnify pursuant to such section [*] after receiving written notice of such Third Party Claim, it being understood and agreed, however, that the failure or delay by an Indemnified Party to timely give such notice shall not affect the indemnification provided hereunder except to the extent the Indemnifying Party is actually and materially prejudiced as a result of such failure or delay to give notice.

10.3.2 **Procedure.** The Indemnifying Party shall assume and conduct the defense of the Third Party Claim using counsel of its choice; provided, however, that the Indemnified Party may participate in and monitor such defense with counsel of its choice at its own expense, subject to the Indemnifying Party's right to control such defense. With respect to any Third Party Claim for which the Indemnifying Party has assumed the defense: [*]. If the Parties cannot agree as to the application of Section 10.1 or Section 10.2 to any Third Party Claim, pending resolution of the dispute pursuant to Section 12.5, the Parties may conduct separate defenses of such Third Party Claim(s), with each Party retaining the right to claim indemnification from the other Party in accordance with Section 10.1 or Section 10.2, as applicable, upon resolution of the underlying claim. If the Indemnifying Party does not assume and conduct the defense of the Third Party Claim as provided above, [*].

10.4 Insurance. [*], each Party, at its own expense, shall maintain commercial general liability insurance, including product liability and other appropriate insurance in an amount

consistent with industry standards in light of its obligations under this Agreement. Each Party shall provide the other Party with evidence of such insurance upon request and shall provide such other Party with [*] prior to the cancellation, non-renewal or material changes in such insurance. Such insurance shall not be construed to create a limit of a Party's liability under this Agreement.

10.5Limitation of Liability. NEITHER PARTY OR ITS AFFILIATES SHALL BE LIABLE TO THE OTHER PARTY OR ITS AFFILIATES FOR (A) ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE OR INDIRECT DAMAGES, OR (B) ANY LOSS OF PROFITS OR REVENUE, IN EACH CASE ((A) OR (B)) ARISING FROM OR RELATING TO THIS AGREEMENT, REGARDLESS OF WHETHER SUCH CLAIM IS IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, AND REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 10.5 IS INTENDED TO OR SHALL LIMIT OR RESTRICT [*].

ARTICLE 11
TERM AND TERMINATION

11.1Term. This Agreement shall be effective commencing on the Effective Date and shall expire in its entirety upon the expiration of the last to expire Royalty Term with respect to all Licensed Products in the Day One Territory (the "**Term**"), unless terminated earlier in accordance with this Article 11 or by mutual written agreement of the Parties. Following the expiration of the Royalty Term for a Licensed Product in a country, the license grant to Day One under Section 2.1 shall become non-exclusive, fully paid-up, royalty-free, perpetual, and irrevocable for such Licensed Product in such country. Upon the expiration of the Term, (a) the license granted to Day One under Section 2.1 shall become non-exclusive, transferable, sublicensable, fully paid, royalty free, perpetual, and irrevocable in its entirety and (b) the license granted to MabCare under Section 2.2 shall become non-exclusive, transferable, sublicensable, fully paid, royalty free, perpetual, and irrevocable in its entirety with respect to Licensed Products being actively clinically Developed or Commercialized as of the effective date of such expiration.

11.2Termination by Day One for Convenience. Day One may terminate this Agreement for convenience in its entirety or on a Licensed Product-by-Licensed Product basis, in each case [*].

11.3Termination for Material Breach. Each Party shall have the right to terminate this Agreement immediately in its entirety upon written notice to the other Party if such other Party materially breaches this Agreement and has not cured such breach [*] following receipt of notice of such breach from the non-breaching Party (or, with respect to any payment breach, [*]); provided however, that if the breach is not a payment breach, and is capable of being cured, but cure of such breach cannot reasonably be effected within such [*], then the cure period shall be extended an additional [*] (for a total of [*] following receipt of notice of such breach from the non-breaching Party). Notwithstanding the foregoing, (i) if the allegedly breaching Party disputes in good faith the existence or materiality of a breach specified in a notice provided by the other Party, and such allegedly breaching Party provides the other Party notice of such dispute [*].

11.4Termination for Bankruptcy.

11.4.1**Right to Terminate**. Each Party shall have the right to terminate this Agreement effective immediately upon delivery of written notice to the other Party in the event that (i) such other Party files in any court or agency pursuant to any statute or regulation of any jurisdiction a petition in bankruptcy or insolvency or for reorganization or similar arrangement for the benefit of creditors or for the appointment of a receiver or trustee of such other Party or its assets, (ii) such other Party is served with an involuntary petition against it in any insolvency proceeding and such involuntary petition has not been stayed or dismissed within sixty (60) days of its filing, or (iii) such other Party makes an assignment of substantially all of its assets for the benefit of its creditors (each of (i) through (iii), an "**Insolvent Event**").

11.4.2**Rights in Bankruptcy**. All rights and licenses granted under or pursuant to this Agreement by one Party to the other Party are, and otherwise will be deemed to be, for purposes of Section 365(n) of Title 11 of the United States Code ("**U.S. Bankruptcy Code**") or comparable provision of applicable bankruptcy or insolvency laws, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws. In the event that a case under the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws is commenced by or against a Party, the other Party shall have all of the rights and elections set forth in Section 365(n) or comparable provision of applicable bankruptcy or insolvency laws to the maximum extent permitted thereby. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a Party under U.S. Bankruptcy Code or any comparable provision of applicable bankruptcy or insolvency laws, the other Party shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in such other Party's possession, shall be promptly delivered to such other Party (i) upon any such commencement of a bankruptcy proceeding upon such other Party's written request therefor, unless such Party elects to continue to perform all of its obligations under this Agreement, or (ii) if not delivered under clause (i), following the rejection of this Agreement by such Party upon written request therefor by such other Party. The Parties agree that they intend the following rights to extend to the maximum extent permitted by law in the case an Insolvent Event occurs with respect to a licensor, including for purposes of the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws: (a) the right of access to any intellectual property (including all embodiments thereof) of the licensor, or any Third Party with whom the licensor contracts to perform an obligation of such licensor under this Agreement which is necessary for the Development, Manufacture or Commercialization of Licensed Compounds and Licensed Products; (b) the right to contract directly with any Third Party described in (a) to complete the contracted work and (c) the right to cure any default under any such agreement with a Third Party and set off the costs thereof against amounts payable to such licensor under this Agreement.

11.5 MabCare Remedy for Patent Challenge. If Day One or any of its Affiliates directly or indirectly takes any action, or knowingly provides assistance to any Third Party, to challenge in a court or administrative proceeding any claim in any MabCare Patent as being invalid, unenforceable or otherwise not patentable ("**Patent Challenge**"), then MabCare, at its discretion, may give notice to Day One that MabCare will terminate the Agreement unless such Patent Challenge is withdrawn, abandoned or terminated (as appropriate) [*] from the date of such notice. If Day One or its Affiliate (as the case may be) does not withdraw, abandon or terminate

(as appropriate) such Patent Challenge within such [*] then, subject to the remainder of this Section 11.5, MabCare may terminate this Agreement. In the event that MabCare notifies Day One in writing that any Sublicensee has initiated a Patent Challenge, then Day One shall terminate such Sublicensee's sublicense agreement in its entirety, unless such action by such Sublicensee is withdrawn [*] after MabCare's notice to Day One thereof. This Section 11.5 does not apply to, and MabCare shall have no right to terminate in the event that, [*].

11.6Termination for Cessation of Development and Commercialization. If following [*] there is a consecutive 24-month period during which Day One, its Affiliates and Sublicensees do not conduct any material Development or Commercialization activities with respect to any Licensed Compound or Licensed Product in or for any Major Market (the "**Cessation Period**"), then MabCare will have the right to terminate this Agreement pursuant to Section 11.3 (for clarity, subject to the cure period and resolution of any dispute with respect to such termination pursuant to Section 11.3). Such Cessation Period shall be tolled to the extent that such cessation is [*].

11.7Full Force and Effect During Notice Period. This Agreement shall remain in full force and effect during the period commencing on the date of notice of termination of this Agreement and ending on the effective date of termination of this Agreement, including any payment obligations accrued during such notice period, even if the due date of such payment may come after the effective date of the termination.

11.8Modification in Lieu of Termination. [*]

11.8.1[*]

11.8.2[*]

11.8.3[*]

11.8.4[*]

11.9Effect of Termination.

11.9.1**Termination in the Entirety**. Without limiting any other legal or equitable remedies that either Party may have under this Agreement, in the event of termination of this Agreement in its entirety for any reason, the terms of this Section 11.9.1 will apply as of the effective date of such termination.

(a)**License**. All rights and licenses granted by a Party to the other Party pursuant to this Agreement shall terminate, and, subject to Section 11.9.1(b), all sublicenses granted hereunder by a Party or its Affiliates shall also terminate, provided that the rights and licenses granted to Day One hereunder shall survive to the extent necessary for Day One (and its Affiliates and Sublicensees) to conduct its rights and obligations under this Section 11.9.1.

(b)**Sublicense Survival**. Notwithstanding anything to the contrary in Section 11.9.1, at each Day One Sublicensee's written request [*] following the effective date of termination, MabCare shall grant to such Sublicensee a direct license on the same terms and

conditions as the sublicense between Day One and such Sublicensee, provided that [*].

(c) **Winddown; Sell-Off**. Day One shall be responsible for the prompt wind-down of Day One's, its Affiliates' and its Sublicensees' Development, Manufacturing and Commercialization of Licensed Compounds and Licensed Products in the Territory in compliance with Applicable Laws; provided that [*] Day One and its Affiliates and Sublicensees shall have the right to sell or otherwise dispose of all Licensed Products then in its or their respective inventory and any in-progress inventory, provided further that Day One shall continue to make payments to MabCare on Net Sales of such Licensed Products in accordance with Section 6.4. If, as of the effective date of termination, Day One or its Affiliates are conducting any Clinical Trials for a Licensed Product, then Day One and its Affiliates shall conduct the orderly wind-down of any such Clinical Trial in accordance with Applicable Law and taking into account patient safety matters.

11.9.2 **Reversion Products**. Subject to any Sublicensee's right under Section 11.9.1(b), with respect to any Licensed Product being [*] as of the effective date of termination of this Agreement (in the form as it exists on the effective date of termination, a "**Reversion Product**"), [*]

11.9.3 **Effects of Termination-in-Part**. Without limiting any other legal or equitable remedies that either Party may have under this Agreement, in the event of any termination of this Agreement in part with respect to one (1) or more Licensed Product(s) pursuant to Section 11.2 or Section 11.3, then Section 11.9.1 shall apply accordingly, but solely with respect to the terminated Licensed Product(s).

11.10 Confidential Information. Upon the expiration or termination of this Agreement in its entirety, at the disclosing Party's election, the receiving Party shall return or destroy all tangible materials to the extent comprising, bearing or containing any Confidential Information of the disclosing Party that are in receiving Party's or its Affiliates' possession or control and provide written certification of such destruction (if applicable) to the disclosing Party, provided that the receiving Party may retain one (1) copy of such Confidential Information for its archives solely to monitor compliance with its obligations herein or may retain such Confidential Information for which it has any continuing rights, and provided further that the receiving Party shall not be required to destroy electronic files containing such Confidential Information that are made in the ordinary course of its business information back-up procedures.

11.11 Termination Not Sole Remedy. Termination is not the sole remedy under this Agreement and, whether or not termination is effected and notwithstanding anything contained in this Agreement to the contrary, all other remedies in law or equity shall remain available except as agreed to otherwise herein.

11.12 Survival. Expiration or termination of this Agreement shall not relieve the Parties of any obligation or right accruing prior to such expiration or termination. In addition, the following provisions of this Agreement shall survive expiration or termination of this Agreement: [*]

ARTICLE 12

MISCELLANEOUS

12.1 Assignment; Notice of Sale.

12.1.1 **Generally**. This Agreement may not be assigned or transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party in whole or in part without the prior written consent of the other Party. Notwithstanding the foregoing, either Party shall have the right, without the prior written consent of the other Party, to assign or transfer this Agreement to an Affiliate or to a successor in interest in connection with a Change of Control or a sale of all or substantially all of its assets to which this Agreement relates. A Party shall notify the other Party in writing of any assignment or transfer of this Agreement by such Party as soon as practicable following such event. The terms of this Agreement will be binding upon and will inure to the benefit of the successors, heirs, administrators and permitted assigns of the applicable Party. Any attempted assignment not in accordance with this Section 12.1 shall be void. Any permitted assignee shall assume all assigned obligations of its assignor under this Agreement.

12.1.2 **Effect of Change of Control**. Whether or not this Agreement is assigned pursuant to Section 12.1.1, the Parties agree that [*].

12.2 Use of Affiliates. Either Party shall have the right to exercise its rights and perform its obligations under this Agreement through any of its Affiliates, provided that any breach of the terms or conditions of this Agreement by such Affiliate shall be deemed a breach by such Party of such terms or conditions.

12.3 Severability. Should one or more of the provisions of this Agreement become void or unenforceable as a matter of Applicable Law, then this Agreement shall be construed as if such provision were not contained herein and the remainder of this Agreement shall be in full force and effect, and the Parties will use their best efforts to substitute for the invalid or unenforceable provision a valid and enforceable provision that conforms as nearly as possible with the original intent of the Parties.

12.4 Governing Law; English Language. This Agreement shall be governed by and construed in accordance with the laws of the State of New York without reference to any rules of conflict of laws that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. The United Nations Convention on Contracts for the International Sale of Goods (CISG) of 11 April 1980 shall not be applicable. This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement.

12.5 Dispute Resolution.

12.5.1 **Disputes**. Any dispute, controversy or claim arising from or related to this Agreement, including the formation, existence, validity, enforceability, performance, interpretation, breach, or termination hereof or thereof (a "**Dispute**") that is not an "Excluded Claim" (as defined below) shall be finally resolved in accordance with Section 12.5.2. Notwithstanding the foregoing, any decisions that are subject to the final decision-making authority of a Party (or mutual agreement of the Parties, as applicable), or the JSC, in each case as

expressly set forth in this Agreement, will not be subject to the provisions of this Section 12.5 so long as such decisions are made in accordance with this Agreement.

12.5.2**Early Resolution; Arbitration.**

(a)**Early Resolution.** [*]

(b)**Arbitration**. [*].

(c)**Confidentiality**. Except to the extent necessary to comply with Applicable Law, legal process or a court order or to enforce a final settlement agreement or secure enforcement of any arbitration award, the Parties agree that the existence, terms and content of any arbitration pursuant to Section 12.5.2(b), all information and documents disclosed in any such arbitration or evidencing any such arbitration results, award, judgment or settlement, or the performance thereof, and any allegations, statements and admissions made or positions taken by either Party in any such arbitration, shall be treated and maintained in confidence and are not intended to be used or disclosed for any other purpose or in any other forum.

12.5.3 **Excluded Claims**. As used in this Section 12.5, the term “Excluded Claim” means a dispute, controversy or claim that concerns (a) the validity or infringement of a Patent Right, trademark, copyright or trade secret, or (b) any antitrust-, anti-monopoly- or competition-related Applicable Law. Any action concerning Excluded Claims may be brought in any court having jurisdiction.

12.5.4**Equitable Relief**. Nothing in this Section 12.5 shall preclude either Party from seeking equitable relief or interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction or other interim equitable relief, either prior to or during any mediation or arbitration, to protect the interests of such Party or to preserve the status quo pending the mediation or arbitration proceeding.

12.6Force Majeure. Except for payment obligations hereunder, neither Party shall be responsible to the other for any failure or delay in performing any of its obligations under this Agreement or for other nonperformance hereunder, if such delay or nonperformance is caused by strike, fire, flood, earthquake, accident, war, act of terrorism, epidemic or pandemic, act of God or of the government of any country or of any local government (including emergency shut-down, lock-down or stay-at-home orders) or by any other cause unavoidable or beyond the control of any Party hereto (“**Force Majeure**”). In such event, the Party affected will provide prompt notice thereof to the other Party and will use all reasonable efforts to resume performance of its obligations and will keep the other Party informed of actions related thereto, and the performance of any obligations of the Party not so affected, which obligations are directly dependent upon such performance by the affected Party, shall be tolled during such period. If any such failure or delay in a Party’s performance hereunder [*].

12.7Language for Communications. All communications and notices to be made or given by one Party to the other Party pursuant to this Agreement will be in the English language. If any data, information, documentation or other materials required to be delivered by a Party to the other Party under this Agreement are not already in English, then, together with the original

form, such Party will provide to the other Party a full English translation of such data, information, documentation or other materials at such Party's cost and expense, provided that if the requesting Party requires a full certified English translation of any such data, information, documentation or other materials, then the requesting Party shall bear the costs of such certified English translation.

12.8Waivers and Amendments. The waiver by either Party of any right hereunder, or of any failure of the other Party to perform, or of any breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach by or failure of such other Party whether of a similar nature or otherwise. Any waivers under this Agreement must be in writing to be effective. No provision of this Agreement may be amended or modified other than by a written document signed by authorized representatives of each Party.

12.9Relationship of the Parties. The Parties relationship is that of independent contractors under this Agreement, and nothing contained herein is intended or is to be construed so as to constitute a Party as a partner, agent, or joint venturer of the other Party. In addition, nothing in this Agreement shall be construed to give a Party the power or authority to act for, bind or commit the other Party to any contract, agreement, or undertaking with any Third Party.

12.10Notices. All notices, consents or waivers under this Agreement shall be in writing and will be deemed to have been duly given when (a) scanned and converted into a portable document format file (i.e., pdf file) and sent as an attachment to an e-mail message, where, when such message is received, a read receipt e-mail is received by the sender, or (b) the earlier of when received by the addressee or five (5) days after the date it was sent, if sent by registered mail or overnight courier by an internationally recognized overnight delivery service (receipt requested), in each case to the appropriate addresses or e-mail addresses set forth below (or to such other addresses and e-mail addresses as a Party may designate by notice):

abCare:

copy to (which shall not constitute notice) to:

[*]

ay One:

[*]

with a copy (which shall not constitute notice) to:

[*]

12.11No Third Party Beneficiary Rights. This Agreement is not intended to and shall not be construed to give any Third Party any interest or rights (including any Third Party

beneficiary rights) with respect to or in connection with any agreement or provision contained herein or contemplated hereby.

12.12 Registration of License. Day One shall have the right to register the exclusive rights and licenses granted by MabCare to Day One under this Agreement with the relevant Governmental Authority in a country or other jurisdiction of the Day One Territory (subject to Article 7). MabCare shall reasonably and promptly cooperate with Day One's efforts to obtain and maintain any such registration, including by promptly executing any forms (including confirmatory licenses) or other documents submitted to MabCare by Day One from time to time in order to effect such registration in a country or other jurisdiction, and the Parties will coordinate to apply for confidentiality protection in connection with such registration to the extent permitted by Applicable Laws.

12.13 Further Assurances. MabCare and Day One hereby agree without the necessity of any further consideration to execute, acknowledge and deliver any and all documents and take any ministerial action as may be reasonably necessary to carry out the intent and purposes of this Agreement.

12.14 Entire Agreement. This Agreement, including all Schedules hereto, sets forth the entire agreement and understanding of the Parties as to the subject matter hereof, and supersedes all proposals, oral or written, and all other communications between the Parties with respect to such subject matter, including the CDA.

12.15 Counterparts. This Agreement may be executed in counterparts with the same effect as if both Parties had signed the same document. All such counterparts shall be deemed an original, shall be construed together, and shall constitute one and the same instrument. Any such counterpart, to the extent delivered by means of a fax machine or by .pdf, .tif, .gif, .jpeg or similar attachment to electronic mail (any such delivery, an "**Electronic Delivery**") shall be treated in all manners and respects as an original executed counterpart and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person. No Party hereto shall raise the use of Electronic Delivery to deliver a signature or the fact that any signature or agreement or instrument was transmitted or communicated through the use of Electronic Delivery as a defense to the formation of a contract, and each Party forever waives any such defense, except to the extent that such defense relates to lack of authenticity.

12.16 Expenses. Each Party shall pay its own costs, charges and expenses incurred in connection with the negotiation, preparation and signing of this Agreement.

12.17 Construction; Interpretation.

12.17.1 **Construction**. The Parties hereto acknowledge and agree that (a) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision, and (b) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement.

12.17.2 **Interpretation**. The captions and headings in this Agreement are

for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement. Unless specified to the contrary, references to Articles, Sections or Schedules mean the particular Articles, Sections or Schedules of or to this Agreement and references to this Agreement include all Schedules hereto. If any conflict exists between the main body of this Agreement and any Schedule hereto, the main body of this Agreement shall prevail. Unless context otherwise clearly requires, whenever used in this Agreement: (a) the words “include” or “including” shall be construed as incorporating, also, “but not limited to” or “without limitation;” (b) the word “day” or “year” means a calendar day or year unless otherwise specified; (c) the words “hereof,” “herein,” “hereby” and derivative or similar words refer to this Agreement as a whole and not merely to the particular provision in which such words appear; (d) the words “shall” and “will” have interchangeable meanings for purposes of this Agreement; (e) the word “or” shall have the inclusive meaning commonly associated with “and/or”; (f) words of any gender include the other genders; (g) words using the singular or plural number also include the plural or singular number, respectively; and (h) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement law, rule or regulation thereof.

12.18 Cumulative Remedies. No remedy referred to in this Agreement is intended to be exclusive unless explicitly stated to be so, and each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

12.19 Export. This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries which may be imposed upon or related to Day One or MabCare from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other Governmental Authority approval, without first obtaining the written consent to do so from the appropriate Governmental Authority.

[*Signature Page follows*]

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Agreement to be executed by their duly authorized representatives.

Day One Biopharmaceuticals, Inc.	**MabCare Therapeutics**
By: /s/ Jeremy Bender	By: /s/ Tao Meng
Name: Jeremy Bender	Name: Tao Meng
Title: Chief Executive Officer	Title: Chief Executive Officer

[Signature Page to Exclusive License Agreement]

List of Schedules:

Schedule 1.14 CB-002
Schedule 1.103 MabCare Materials
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Schedule 1.14

CB-002 Description

[*]

Schedule 1.103

MabCare Material(s)

[*]

Schedule 1.104

MabCare Patents

Application NO.	Filing date	National /Regional phase entry date	Title	Applicant	Inventor	Country/Region	Publication NO.	Publication Date
[*]	[*]	[*]	[*]	[*]	[*]	[*]	[*]	[*]

Schedule 4.1.2

Transferred Regulatory Materials

[*]

Schedule 4.1.3

Existing Inventory

[*]

Schedule 4.4.1

[*]

Schedule 5.2

Term Sheet of Clinical Supply Agreement

Summary	[*]
Manufacture and Supply	[*]
Subcontracting	[*]
Forecast, Orders	[*]
Delivery Terms	[*]
Supply Price; Payment	[*]
Quality & Documentation	[*]
Manufacturing Representations and Warranties	[*]
Inspection, Acceptance and Rejection	[*]
Responsibilities of Day One	[*]
Governing Law; Dispute Resolution	[*]
Other Customary Provisions	[*]

Schedule 7.5.1

Press Release

Day One Expands Pipeline with Potential First-in-Class Clinical-Stage Antibody Drug Conjugate (ADC) Targeting PTK7 in Solid Tumors for Adult and Pediatric Cancers

Day One receives exclusive license for development and commercialization of MTX-13 (DAY301), which received IND clearance by the FDA in April 2024

Targets PTK7, highly expressed in broad range of adult and pediatric solid tumors

BRISBANE, Calif., June X, 2024 – Day One Biopharmaceuticals (Nasdaq: DAWN) ("Day One" or the "Company"), a commercial-stage biopharmaceutical company dedicated to developing and commercializing targeted therapies for people of all ages with life-threatening diseases, today announced it has entered into an exclusive licensing agreement (the Agreement) with MabCare Therapeutics (MabCare) for MTX-13, a novel ADC targeting protein-tyrosine kinase 7 (PTK7). Pursuant to the terms of the Agreement, Day One has exclusive rights to develop, manufacture, and commercialize MTX-13 worldwide, excluding Greater China.

In April 2024, the U.S. Food and Drug Administration (FDA) cleared the investigational new drug (IND) application for MTX-13, which going forward will be identified as DAY301. In pre-clinical studies, DAY301 showed antitumor activity in a wide range of solid tumors.

"Our priorities for 2024 are to successfully launch OJEMDA™ (tovorafenib), to advance our existing programs and to expand our pipeline by in-licensing clinical-stage assets that have the potential to transform outcomes for patients of all ages living with cancers," said Jeremy Bender, Ph.D., chief executive officer of Day One. "We are excited by the opportunity presented by DAY301, and we believe we have the right team in place to develop the program to its full potential."

DAY301 targets PTK7, a highly-conserved, catalytically inactive transmembrane protein that is overexpressed in multiple adult cancers, including esophageal, ovarian, lung, and endometrial cancer, as well as pediatric cancers such as neuroblastoma, rhabdosarcoma and osteosarcoma. PTK7 has limited expression in normal tissues or organs, making it an attractive target for therapeutic development.

"The addition of DAY301 to our pipeline strategically fits our mission of advancing both pediatric and adult medicines in areas of unmet need with equal urgency," said Dr. Samuel Blackman, co-founder and head of research and development at Day One. "We believe the linker-payload technology embodied in DAY301 will overcome the limitations of earlier PTK7-targeted ADCs, giving us a potential first-in-class

drug against a clinically-validated target. We are excited to add this program to Day One and will look to enter the clinic in the coming months."

Under the terms of the licensing agreement, MabCare will receive $55 million upfront, and is eligible to receive an additional $1.152 billion in development, regulatory and commercial success-based milestones, plus low-to-mid single-digit royalties on net sales outside of Greater China. Day One expects the first patient to be dosed in the Phase I study in late Q4 2024 or early Q1 2025.

About Day One Biopharmaceuticals
Day One Biopharmaceuticals is a commercial-stage biopharmaceutical company that believes when it comes to pediatric cancer, we can do better. The Company was founded to address a critical unmet need: the dire lack of therapeutic development in pediatric cancer. Inspired by "The Day One Talk" that physicians have with patients and their families about an initial cancer diagnosis and treatment plan, Day One aims to re-envision cancer drug development and redefine what's possible for all people living with cancer—regardless of age—starting from Day One.

Day One partners with leading clinical oncologists, families, and scientists to identify, acquire, and develop important targeted cancer treatments. The Company's pipeline includes tovorafenib (OJEMDA™) and pimasertib.

Day One is based in Brisbane, California. For more information, please visit www.dayonebio.com or find the Company on LinkedIn or X.

Cautionary Note Regarding Forward-Looking Statements
This press release contains "forward-looking" statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to: Day One's plans to develop cancer therapies, including DAY301, expectations regarding planned and current clinical trials and the ability of tovorafenib to treat pLGG or related indications.

Statements including words such as "believe," "plan," "continue," "expect," "will," "develop," "signal," "potential," or "ongoing" and statements in the future tense are forward-looking statements. These forward-looking statements involve risks and uncertainties, as well as assumptions, which, if they do not fully materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements.

Forward-looking statements are subject to risks and uncertainties that may cause Day One's actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties in this press release and other risks set forth in our filings with the Securities and Exchange Commission, including Day One's ability to develop, obtain regulatory approval for or commercialize any product candidate, Day One's ability to protect intellectual property, the potential impact of global business or macroeconomic conditions, including as a result of inflation, rising interest rates, instability in the global banking system, geopolitical conflicts and the sufficiency of Day One's cash, cash equivalents and investments to fund its operations. These forward-looking statements speak only as of the date hereof and Day One specifically disclaims any obligation to update these forward-looking statements or reasons why actual results might differ, whether as a result of new information, future events or otherwise, except as required by law.

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Schedule 9.2.3

MabCare In-License and Other Agreement

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Schedule 9.2.22

INDs, MAAs and Regulatory Approvals
for the Licensed Compounds and Licensed Products

[*]

Schedule 11.9.2

Arbitration Terms relating to Reversion License Dispute

[*]

Exhibit 31.1

CERTIFICATION PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jeremy Bender, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Day One Biopharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 2, 2024

/s/ Jeremy Bender, Ph.D., M.B.A.
Jeremy Bender, Ph.D., MBA
Chief Executive Officer and President
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Charles N. York II, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Day One Biopharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 2, 2024

/s/ Charles N. York II, M.B.A.
Charles N. York II, M.B.A.
Chief Operating Officer and Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Jeremy Bender, Chief Executive Officer of Day One Biopharmaceuticals, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. the Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended June 30, 2024 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 2, 2024

/s/ Jeremy Bender, Ph.D., M.B.A.
Jeremy Bender, Ph.D., MBA
Chief Executive Officer and President
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Charles N. York II, Chief Financial Officer of Day One Biopharmaceuticals, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. the Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended June 30, 2024 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 2, 2024

/s/ Charles N. York II, M.B.A.
Charles N. York II, M.B.A.

Chief Operating Officer and Chief Financial Officer

(Principal Financial Officer and Principal Accounting Officer)